17-19 & 9-17 3D Scanners
Service Manual

Cone Beam Volumetric Tomography and
Panoramic Dental Imaging Systems

IMPORTANT! . . . X-RAY PROTECTION

X-ray equipment may cause injury if used improperly. The instructions contained in this manual must be read and followed when installingthis device. The device provides a high degree of protection from unnecessary X-radiation. However, no practical design can provide complete protection, nor prevent operators from exposing themselves or others to unnecessary radiation. It is important that you become fully acquainted with applicable government radiation protection regulations. Many provisions of these regulations are based on the recommendations of the National Council on Radiation Protection and Measurements. Recommendations for dental X-ray protection are published in NCRP Report Number 35 available from NCRP Publications, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814, or at www.ncrp.com. Personal radiation monitoring and protective devices are available. You are urged to use them to protect against unnecessary X-radiation exposure.

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Chapter 1 Troubleshooting and Corrective Action

Error and Probable Cause	Corrective Action
Chair will not go up or down Loose cable or connection	Check all cable connections; check laser function; check laser & up/down together; check chair linear actuator function.
Stall detected while overhead rotates Improper gear mesh	Check for proper gear mesh between the overhead drive gear and the large overhead gear.
No communication between PC & iCAT Ethernet cable or network card loose	Ping NIC, Embedded Controller & Panel; check ethernet cable between PC and back of machine; replace ethernet cable.
iCAT not powering up Breaker switch turned OFF	Check white breaker switch on top rear of iCAT machine - ensure that it is in the "ON" position.
X-ray not firing Loose cable or connetion	Check all cable connections leading from the x-ray power supply to the x-ray tube head.
Fault light is lit - machine not responsive E-stop engaged	Check patient e-stop for engagement, turn clockwise to release; check e-stop on/off box for engagement, turn clockwise to release.
Ready light is blinking - unable to scan Door interlock switch not engaged	Check door interlock switch for proper engagement, if door is open, close door; if handheld "dead-man" switch - engage properly.
Warning system light not illuminating during x-ray No power to warning system	Check power supply to external warning system (not supplied by ISI); check all wiring to warning system and cable provided.
Acquisition PC not booting Bad or unseated RAM	Check RAM one by one to ensure PC boot; check power from computer power supply; check motherboard.
One side of image is dark after scan Shutter not responding, staying closed	Check collimator calibration for any "Slope" values = "0.0"; remove cover over collimators - locate shutter "test" button on Beam Limiter Control PCB, check for loose connections on shutters, replace chip set w/ spare located on shutter assy.

Chapter 2 Calibration

The Panel, Collimators, and Geometry Calibrations can be conducted by the Owner / Operator of the device or service technicians. It is recommended that the Panel Calibration be performed once a week.

Panel Calibration

The Panel Calibration is performed for both Portrait and Landscape positions. The entire calibration takes approximately 8 to 10 minutes to complete. The process performs a multi-mode calibration as listed below:

17-19 Models:

- Mode 0 (4 x 4) Landscape
- Mode 1 (2 x 2) Landscape
- Mode 2 (2 x 2) PAN (Landscape)
- Mode 3 (4 x 4) Portrait
- Mode 4 (2 x 2) Portrait
- Mode 5 (1 x 1) PAN (Landscape, not supported)

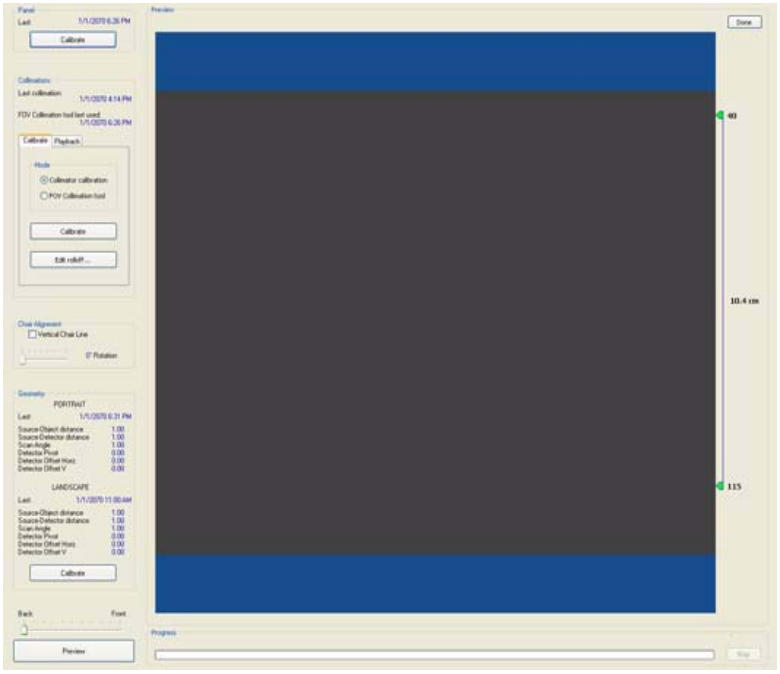
9-17 Models:

- Mode 0 (4 x 4) Landscape
- Mode 1 (2 x 2) Landscape
- Mode 2 (1 x 1) PAN (Landscape, not supported)
- Mode 3 (2 x 2) PAN (Landscape)
- Mode 4 (not supported)
- Mode 5 (4 x 4) Portrait
- Mode 6 (2 x 2) Portrait

To run the Panel Calibration:

1. Ensure room temperature is in the range of 50 to 95°F (10 to 35°C).
2. From the desktop, double click the **Calibration** icon.

The Calibration screen is displayed.



3. Click the **Calibrate** button (top) in the *Panel* field.

WARNING

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the operating instructions. Do not operate this system unless you have received training to perform a procedure.

A window is displayed *"Remove all objects from the field of view and click OK to start X-ray exposure."*

4. Click **OK**.
5. When prompted, press the **Scan** button on the Control Box. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

6. The progress of the scan is displayed on the *Progress* bar at the bottom of the Acquire window. You will be prompted to press the **Scan** button several times as the calibration progresses.

   "Panel Calibration Complete" is displayed when the process is finished. Click **OK**.

Collimators Calibration

It is recommended to perform the Collimators Calibration once a week to ensure optimal image quality. This calibration is also necessary if a mechanical adjustment is made to the Beam Limiter or if image quality has degraded. The Collimator Calibration runs in both Portrait and Landscape positions and takes less than 3 minutes to complete.

CAUTION

The FOV Collimation tool is for German regulatory compliance only. Do NOT use this tool unless you are qualified to do so.

NOTE: A Panel calibration must be performed prior to a Collimators calibration.

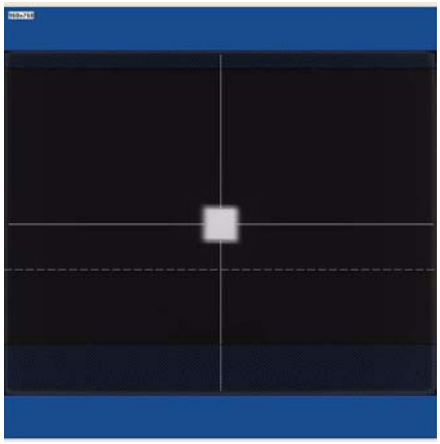
7. In the Collimations field, ensure **Collimator calibration** is selected on the Calibrate tab.
8. Click the **Calibrate** button in the *Collimations* field.

   A window is displayed: *"Starting Collimator Calibration Remove all objects from the field of view and click OK to start X-ray exposure."*

WARNING

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the operating instructions. Do not operate this system unless you have received training to perform a procedure.

9. Click **OK** to start the X-ray exposure.
10. On the Control Box, press **Scan** when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.



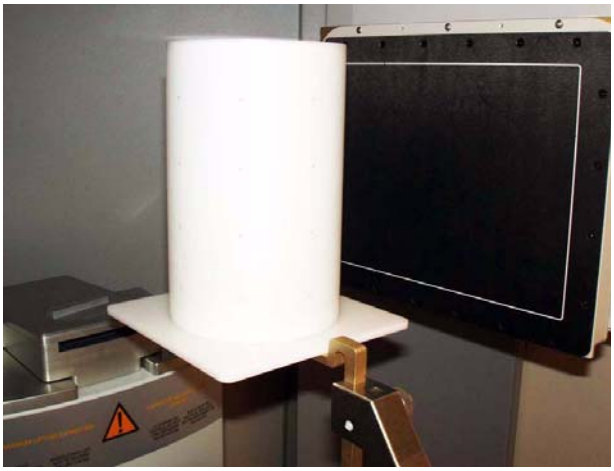
11. The scan starts in the Landscape and continues into the Portrait mode, displaying three screen shots in both modes.
12. Click **OK** when calibration completes (less than 3 minutes)

Geometry Calibration (17-19 Models)

It is recommended to perform the Geometry Calibration once a year to ensure optimal image quality or if the image quality is degraded. The Panel Calibration must be performed prior to this. The Geometry Calibration runs in both Portrait and Landscape positions and takes about 12 to 15 minutes to complete.

Perform Geometry Calibration:

13. Mount the Phantom Platform and center the BB Phantom on the platform using the alignment holes on the bottom of phantom. (shown below).



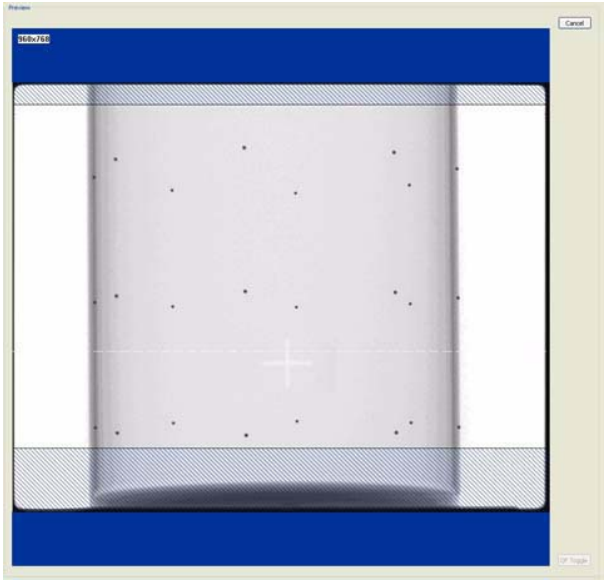
14. Ensure that the BB Phantom is level. Use shims or pieces of paper under the phantom to level it if necessary.
15. Align the BB Phantom crosshair slits with the laser cross beams. For an accurate alignment, the laser beams should penetrate though the phantom crosshair slits and appear on the receptor panel.
16. Click the **Preview** button which is located at the bottom of the Calibration screen.

WARNING

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the operating instructions. Do not operate this system unless you have received training to perform a procedure.

17. The ready window is displayed, click **OK**.
18. On the Control Box, press **Scan** when prompted. An audible alarm is sounded and the X-ray light illuminates during radiation exposure.
19. The BB Phantom image is displayed (shown below).

Back (Volume Center)

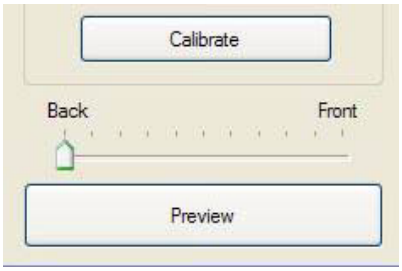


Front (Volume Center)

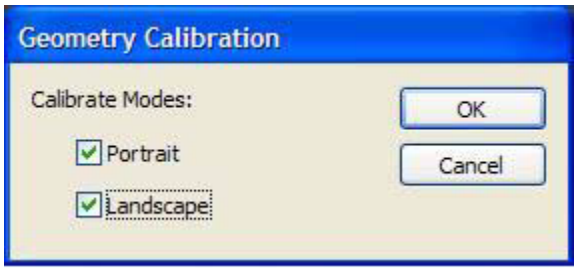
20. Ensure that the phantom is centered, level, and **all** BBs (dots) appear in the Field of View. If required, make adjustments and click **Preview** again. Repeat as required.

Height adjustments are made by raising or lowering the phantom platform. BBs should not touch the top or bottom lines.

To reposition the phantom right or left on the Preview screen, use the **Back / Front** feature.



21. When the BB Phantom is centered and level, click the **Calibrate** button on the Geometry panel (bottom).
22. Select both the Landscape and Portrait calibration modes.



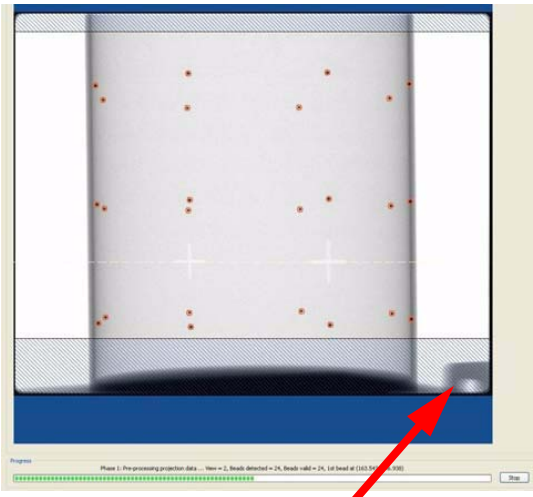
WARNING

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the operating instructions. Do not operate this system unless you have received training to perform a procedure.

23. Click **OK** to start the X-ray exposure.
24. On the Control Box, press **Scan** when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.

25. The calibration starts with the Landscape Scan.

LANDSCAPE SCAN



Metal Platform Support (below FOV)

PORTRAIT SCAN

NOTE: Ensure that the metal platform support is below the Field of View (as shown above.)

26. At the start of the scan, red circles are displayed around each BB. At this point, check data (above green progress bar), to ensure the following is displayed:

    Beads detected = 24, Beads valid = 24

27. At the prompt, press **Scan** on the Control Box, to start the Portrait Scan.

28. During the Portrait Scan, ensure the following is displayed:

    Beads detected = 20, Beads valid = 20

NOTE: Check to ensure that all beads are intact on the BB Phantom, if the calibration did not detect a bead at a certain location.

29. Click **OK** when the completion window is displayed and restart Vision software.

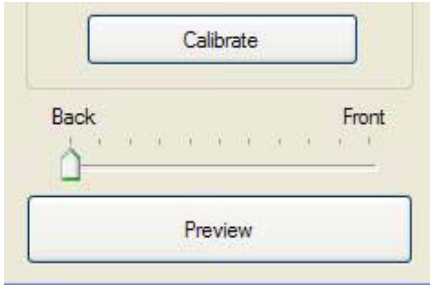
    Failure to restart Vision software at this point may result in a system failure.

Geometry Calibration (9-17 Models)

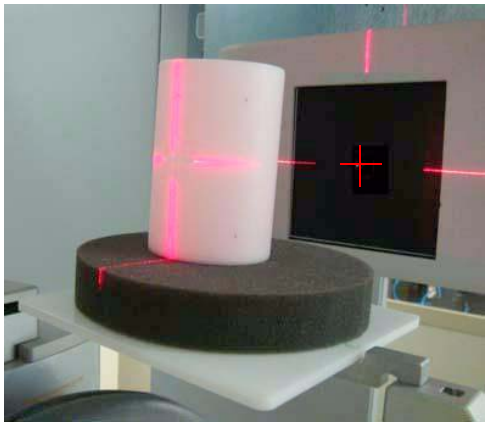
It is recommended to perform the Geometry Calibration once a year to ensure optimal image quality or if the image quality is degraded. The Panel Calibration must be performed prior to this. The Geometry Calibration runs in both Portrait and Landscape positions and takes about 12 to 15 minutes to complete.

Perform Geometry Calibration:

1. Use the **Back / Front** feature to ensure the Panel is set to the back.



2. Place BB Phantom on a piece of foam and center the phantom on the platform.



3. Ensure that the BB Phantom is level. Use shims or pieces of paper under the phantom to level it if necessary.
4. Center the BB Phantom (left to right) using the Front Laser.
5. Align the BB Phantom crosshair slits so that the laser beams penetrate through the phantom crosshair slits and appear on the receptor panel.
6. Click the **Preview** button which is located at the bottom of the Calibration screen.

WARNING

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the operating instructions. Do not operate this system unless you have received training to perform a procedure.

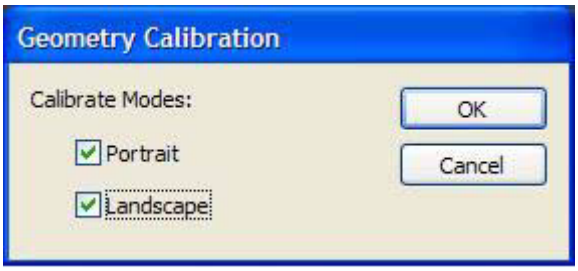
7. The ready window is displayed, click **OK**.
8. On the Control Box, press **Scan** when prompted. An audible alarm is sounded and the X-ray light illuminates during radiation exposure.
9. The BB Phantom image is displayed (shown below).

Back (Volume Center)

Front (Volume Center)

10. Ensure that the phantom is centered, level, and **all** BBs (dots) appear in the Field of View. If required, make adjustments and click **Preview** again. Repeat as required.

    Height adjustments are made by raising or lowering the phantom platform. BBs should not touch the top or bottom FOV.
11. When the BB Phantom is centered and level, click the **Calibrate** button on the Geometry panel (bottom).
12. Select both the Landscape and Portrait calibrate modes.



WARNING

The X-ray device may be dangerous to the Patient and operator if you do not observe and follow the operating instructions. Do not operate this system unless you have received training to perform a procedure.

13. Click **OK** to start the X-ray exposure.
14. On the Control Box, press **Scan** when prompted. An audible alarm is sounded and the X-ray ON light is illuminated during radiation exposure.
15. The calibration starts with the Landscape Scan.

LANDSCAPE SCAN **PORTRAIT SCAN**

Metal Platform Support (below FOV)

NOTE: Ensure that the metal platform support is below the Field of View (as shown above.)

16. At the start of the scan, red circles are displayed around each BB. At this point, check data (above green progress bar), to ensure the following is displayed:

    Beads detected = 12, Beads valid = 12

17. At the prompt, press **Scan** on the Control Box, to start the Portrait Scan.
18. During the Portrait Scan, ensure the following is displayed:

    Beads detected = 8, Beads valid = 8

NOTE: Check to ensure that all beads are intact on the BB Phantom, if the calibration did not detect a bead at a certain location.

19. Click **OK** when the completion window is displayed and restart Vision software.

    Failure to restart Vision software at this point may result in a system failure.

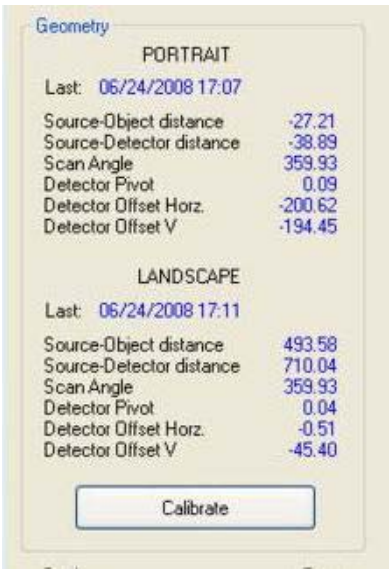
Diagnosing Blurry Image/Failed Reconstruction Due to Bad Geometric Calibration Values

If an image is blurred or doubled, or reconstruction will not complete successfully, perform the following.

1. From the desktop, double click the **Calibration** icon. The Calibration screen is displayed.
2. Check the following values in the Geometry section.
   a. Valid values typically fall within the following ranges:
      - Source-Object distance = 500 (+/- 30)
      - Source-Detector distance = 700 (+/- 30)
      - Scan Angle should always be close to 360
   b. Bad values will be significantly different from these due to a failed geometric calibration. Re-run Portrait and/or Landscape Geometric Calibration to achieve acceptable values.

Example: Good Values

Example: Bad Values



Chapter 3 Illustrated Parts Breakdown

WARNING

High voltage is present in the device. Remove power from device before removing covers or cables. To avoid personal injury from electrical shock, do not operate the system with any covers open or cables removed.

This chapter is used to provided replacement part numbers. Ensure power is removed before servicing the device.

The following Assemblies are illustrated.

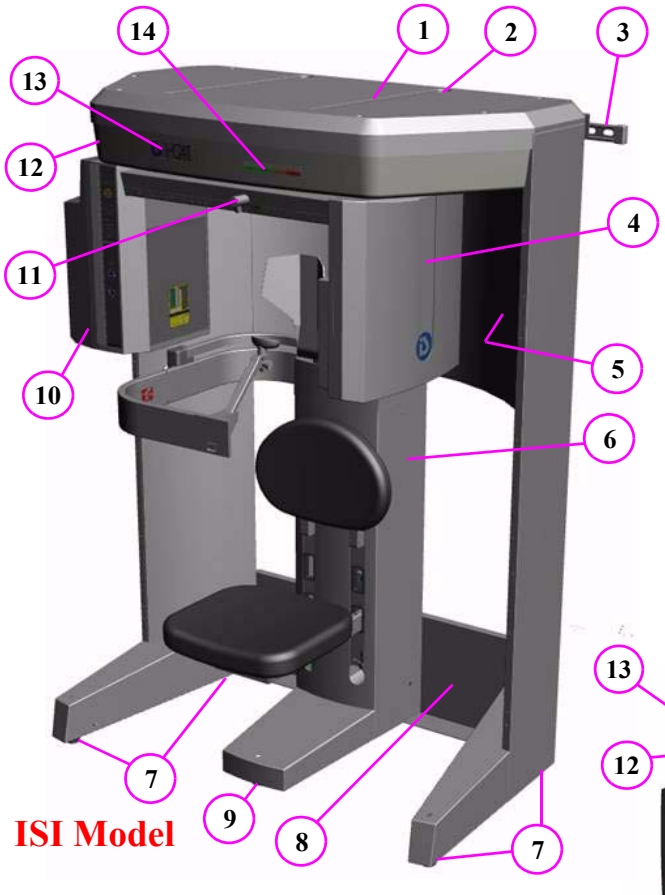
Model 17-19

- *17-19 System Assemblies*
- *17-19 Overhead Assembly*
- *17-19 Rotation Drive Assembly*
- *17-19 X-Ray Source Assembly*
- *17-19 Flip Receptor Panel Assembly (109-0 or K109-0)*
- *17-19 Flip Receptor Panel Assembly (133-0 or K133-0)*
- *17-19 Chair Assembly*
- *17-19 Upper Chair Assembly*

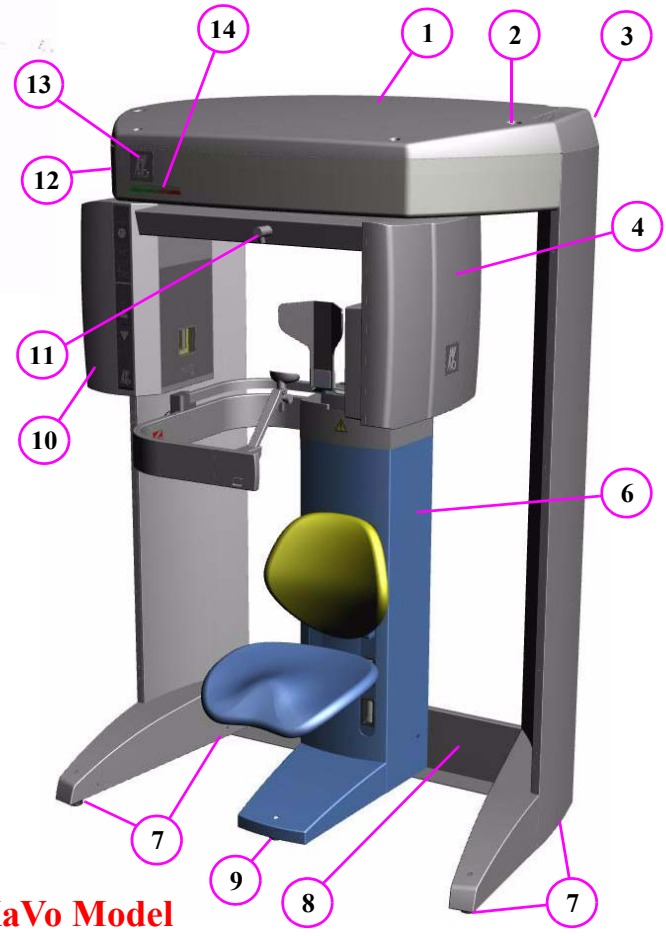
Model 9-17

- *9-17 System Assembly*
- *9-17 Overhead Assembly*
- *9-17 Rotation Drive Assembly*
- *9-17 X-Ray Source Assembly*
- *9-17 Receptor Panel Assembly*
- *9-17 Chair Assembly*
- *9-17 Upper Chair Assembly*

17-19 System Assemblies



ISI Model

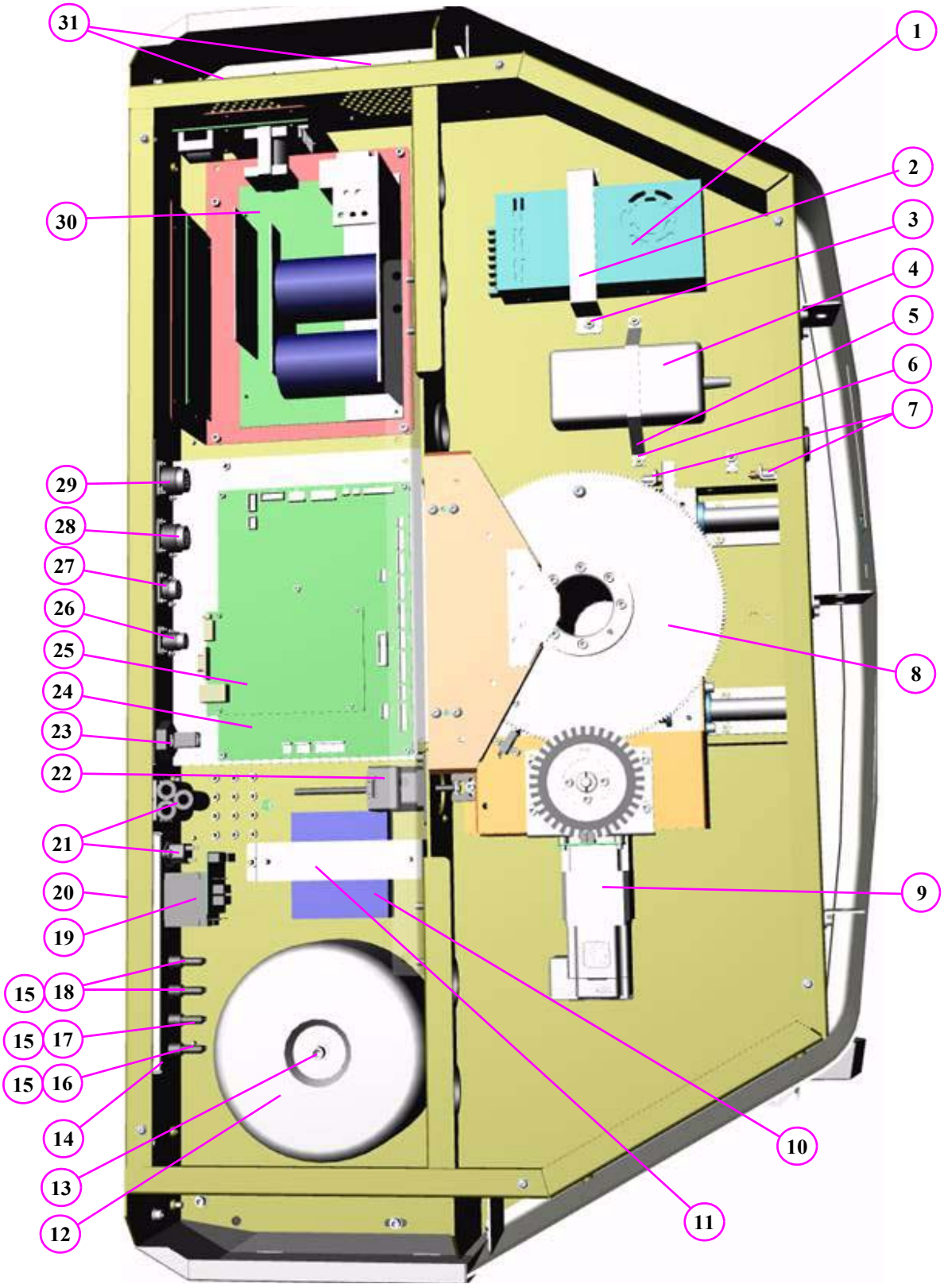


KaVo Model

17-19 System Assembly Parts List

Item	ISI Part No.	KaVo Part No.	Description
1	102-4	K102-4	Upper Cover
2			BHCS #8-32 x 3/8 Long
3	32-0	32-0	Wall Stabilizer
4	109-0 133-0	K109-0 K133-0	Flip Receptor Assembly Flip Receptor Assembly
5	101-7		Rear Scatter Shield
6	20-0	K20-0	Chair Assembly
7	1000031	1000217	IEC #IL8-6B x 3 HX-BC Bottom Chamfer
8	534-0	G534-0	Lower Plate Weldment
9	1000108	1000216	Bottom Chamfer/Leveler
10	106-0	K106-0	X-Ray Source Assembly
11	15-0	15-0	Laser Line Assembly
12	102-3-0	K102-3-0	Lower Cover Assembly
13	1312	K1312	IS i-CAT Logo
14	1302	K1302	Resident Indicator Panel

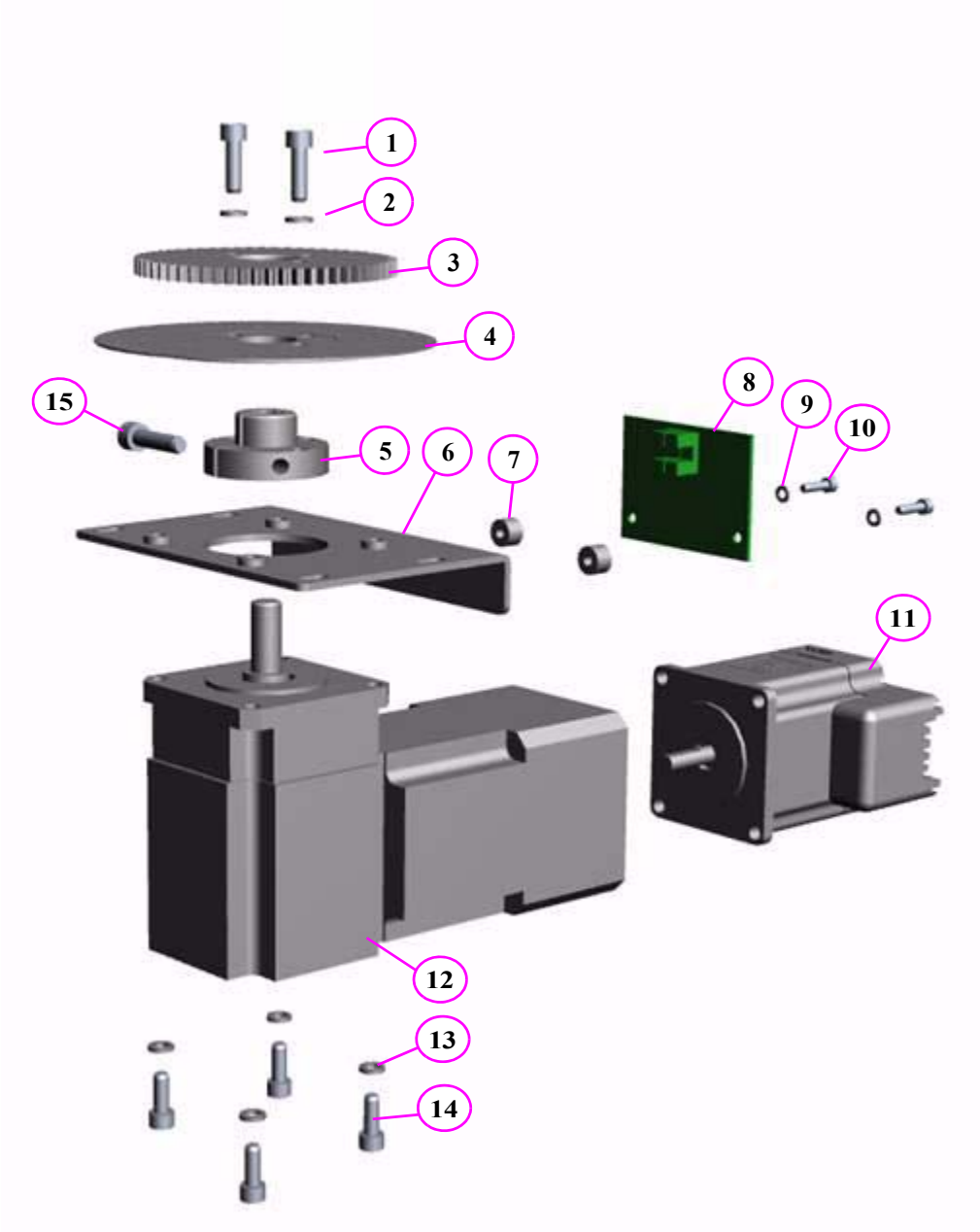
17-19 Overhead Assembly



17-19 Overhead Assembly Parts List

Item	ISI Part No,	KaVo Part No,	Description
1	1000032	1000032	24V Power Supply
2	1000455	1000455	Hook and Loop Fastener
3			#10-32 Nut
4	1000111	1000111	15V Receptor Power Supply
5	1000455	1000455	Hook and Loop Fastener
6			#10-32 Nut
7	1507	1507	Limit Switches (set)
8	9-0	9-0	Spindle Assembly
9	11-0	11-0	Rotation Drive
10	1025-0	1025-0	Network Switch and Power Cable
11	1000455	1000455	Hook and Loop Fastener
12	1701-0	1701-0	Toroid Isolation Transformer
13			SHCS 5/16-18 x 1 Long
14	1015-0-1	K1015-0-1	Power Bracket Assembly
15	1000176	1000176	Buss #HTB-84M
16	1000010	1000010	10A Fuse Digi-Key #F985-ND
17	1000005	1000005	2.5A Fuse Digi-Key #F979-ND
18	1000011	1000011	1/4 A Fuse Digi-Key #F939-ND
19	1255	1255	115VAC Circuit Breaker
	1256	1256	230VAC Circuit Breaker
	1257	1257	200VAC Circuit Breaker
	1258	1258	100VAC Circuit Breaker
20	1310	1310	Fuse Label (not shown)
21	1570	1570	Line Choke
22	102-16	102-16	Stepper Motor Assembly - 17 Frame
23	1557	1557	Ethernet Panel Mount Cable
24	1203	1203	i-CAT System Board
25	1210	1210	i-CAT Computer Board
26	1526	1526	Warning System External Cable Assembly
27	1523	1523	Door Interlock External Cable Assembly
28	1519	1519	Control Box External Cable Assembly
29	1521	1521	Chair External Cable Assembly
30	1000-0	1000-0	X-Ray Power Supply
31	1541	1541	Overhead Fan (pair)

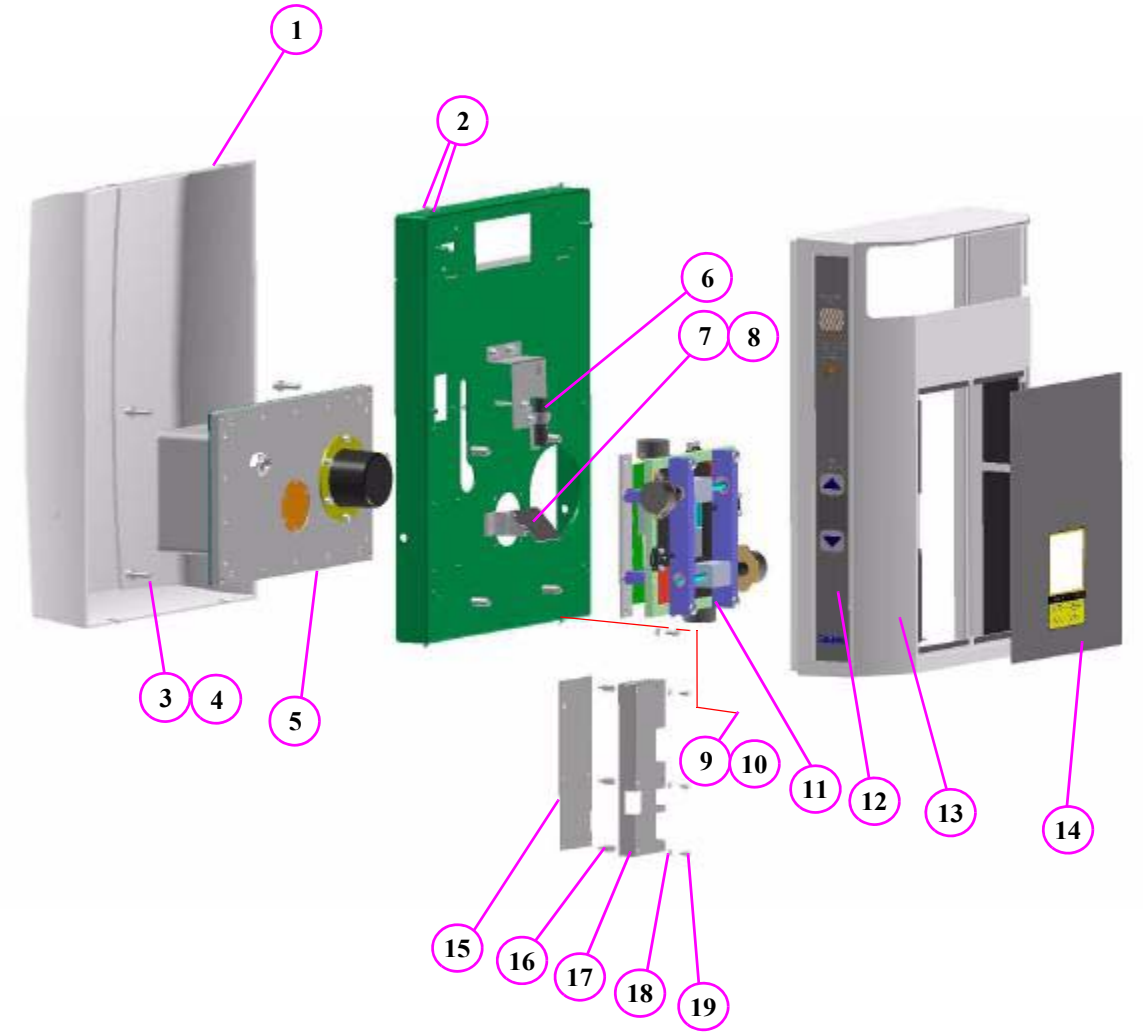
17-19 Rotation Drive Assembly



17-19 Rotation Drive Assembly Parts List

Item	ISI/KaVo Part No.	Description
1		SHCS #10-24 x 5/8 Long
2		Split Washer #10
3	11-5	Drive Gear
4	11-3	Gear Encoder Disk
5	11-4	Gear Clamp
6	11-2	Rotation Motor Bracket
7	1000027	Al. Round Spacer
8	1205	Gear Encoder
9		Split Washer #6
10		SHCS #6-32 x 1/2 Long
11	11-6	Stepper Motor
12	120110	Thomson Micron #NTR23-025
13		Split Washer #10
14		SHCS #10-24 x 1/2 Long
15		SHCS #10-24 x 3/4 Long

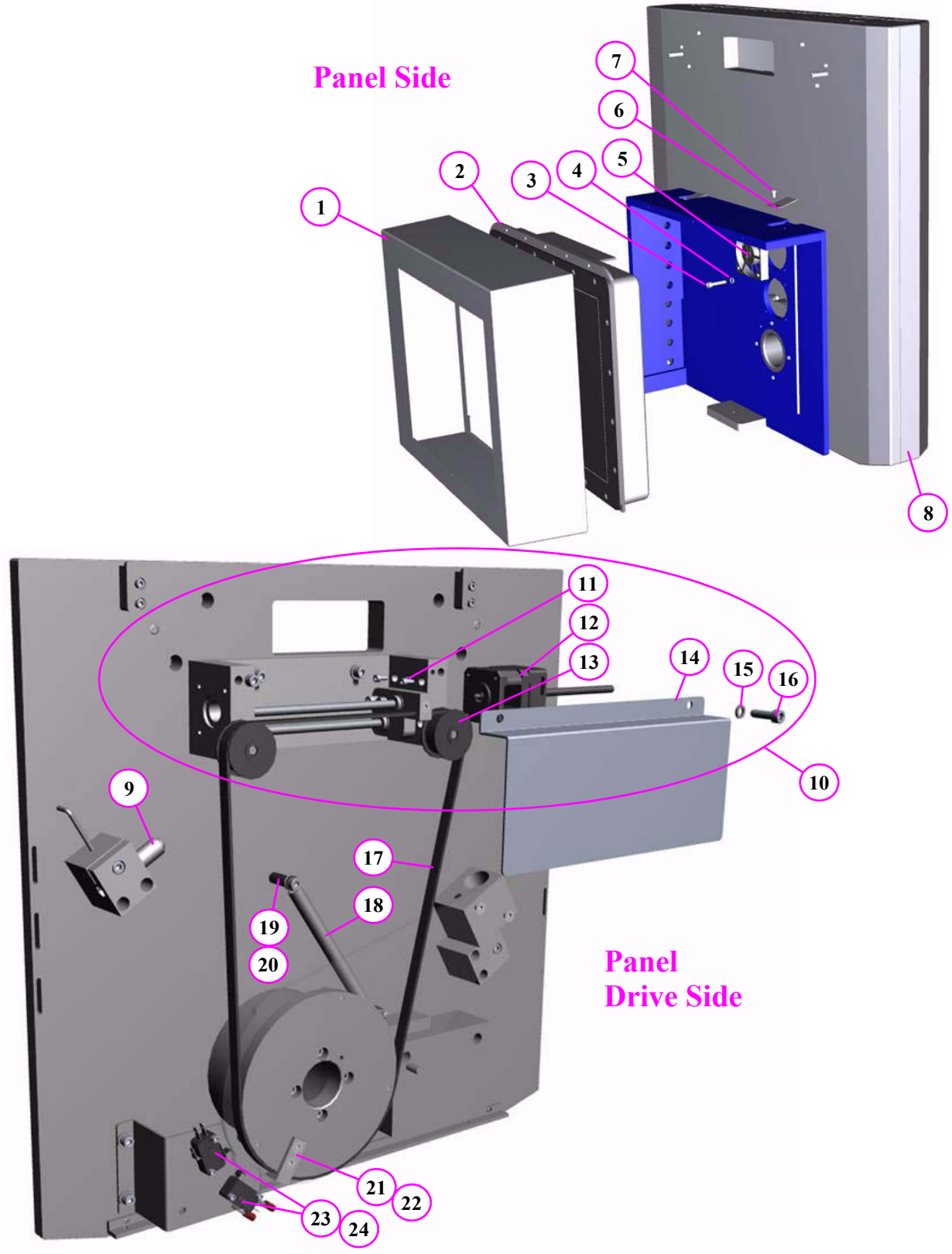
17-19 X-Ray Source Assembly



17-19 X-Ray Source Assembly Parts List

Item	ISI Part No.	KaVo Part No.	Description
1	106-7-0	K106-7-0	Rear X-Ray Source Cover
2			BHCS #8-32 x 1/2 Long
3			SHCS 1/4-20 x 1 Long
4			Split Washer 1/4
5	35-0	35-0	Tube Head
6	1539	1539	Cross Laser Assembly
7	106-24	106-24	Cross Laser Mirror
8			BHCS #6-32 x 1/4 Long
9			Split Washer #10
10			SHCS #10-24 x 3/8 Long
11	147-0	147-0	Beam Limiter
12	1305	K1305	Patient Align Panel
13	106-6-0	K106-6-0	Front X-Ray Source Cover Assembly
14	1308-0	1308-0	Beam Limiter Panel
15	1206	1206	Beam Limiter Control PCB
16	1000211	1000211	#6-32 x 1/2 Long Standoff McMaster #91
17	106-8	106-8	Beam Limiter Board Shield
18			Split Washer #6
19			SHCS #6-32 x 1/4 Long

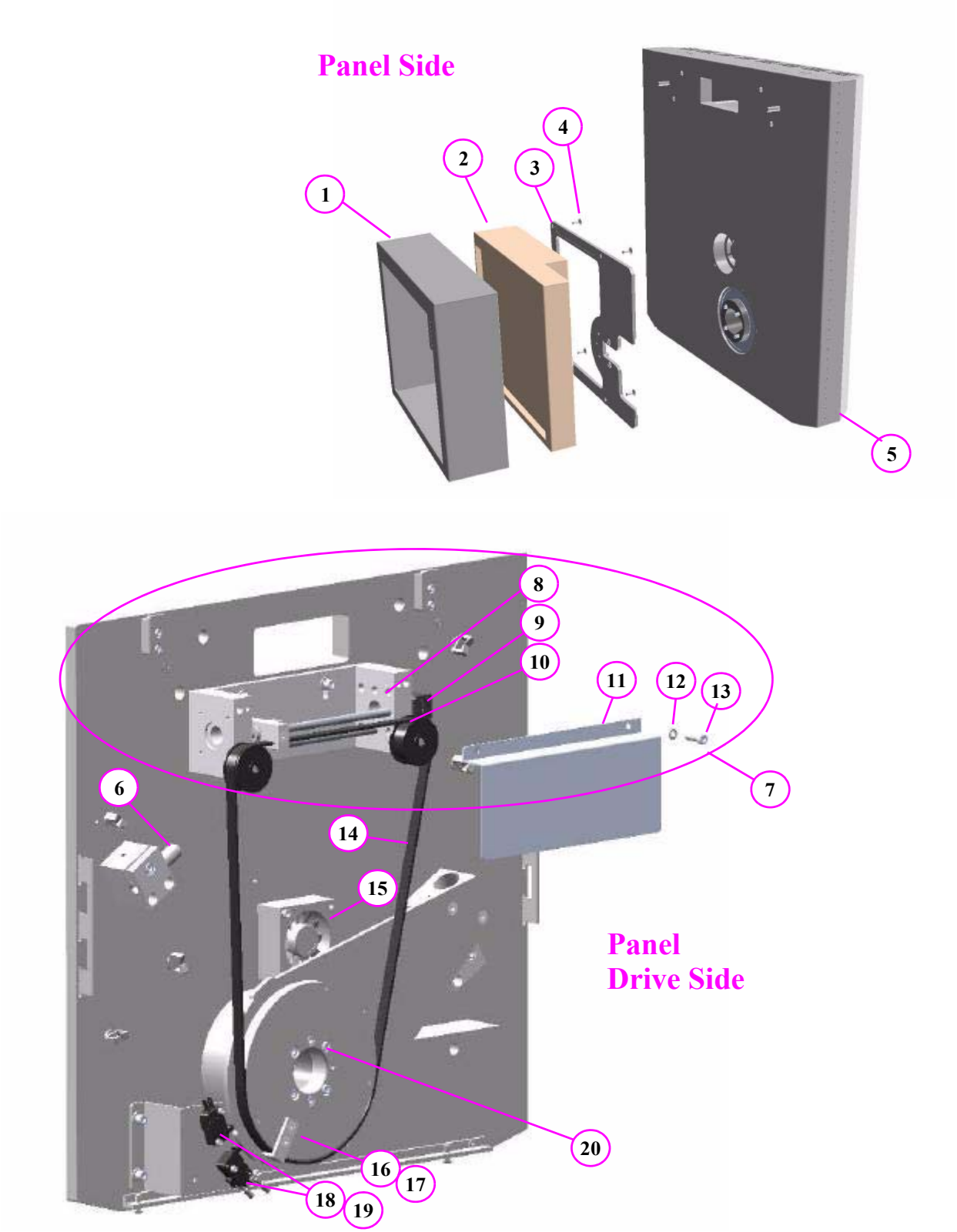
17-19 Flip Receptor Panel Assembly (109-0 or K109-0)



17-19 Flip Receptor Panel Assembly Parts List (109-0 or K109-0)

Item	ISI Part No.	KaVo Part No.	Description
1	109-14	K109-14	Panel Cover
2	800186	800184	Receptor Panel
3			SHCS #8-32 x 3/4 Long
4			Split Washer #8-4
5	1549	1549	Flip Receptor Fan
6	109-11	109-11	Cover Spring
7			BHCS #6-32 x 1/4
8	105-5-0	K105-5-0	Rear Receptor Cover Assembly
9	109-12	109-12	Stop Screw
10	109-0-2	109-0-2	Drive Screw Assembly
11			SHCS M3 x 8mm Long
12	109-2	109-2	Flip Stepper Motor
13	109-31	109-31	Idler
14	109-17	109-17	Cable Shield
15			Split Washer #10
16			SHCS #10-32 x 5/8 Long
17	1000189	1000189	Belt McMaster #6484K511
18			Spring Extension
19	109-18	109-18	Spring Bushing
20			Shoulder Screw 1/4 Diameter x 1” Long x #10-32
21	109-16	109-16	Belt Key
22			Flat Head Screw #8-32 x 3/8 Long
23	1550	1550	Flip Receptor Limit Switch Assembly
24			SHCS #4-40 x 5/8 Long

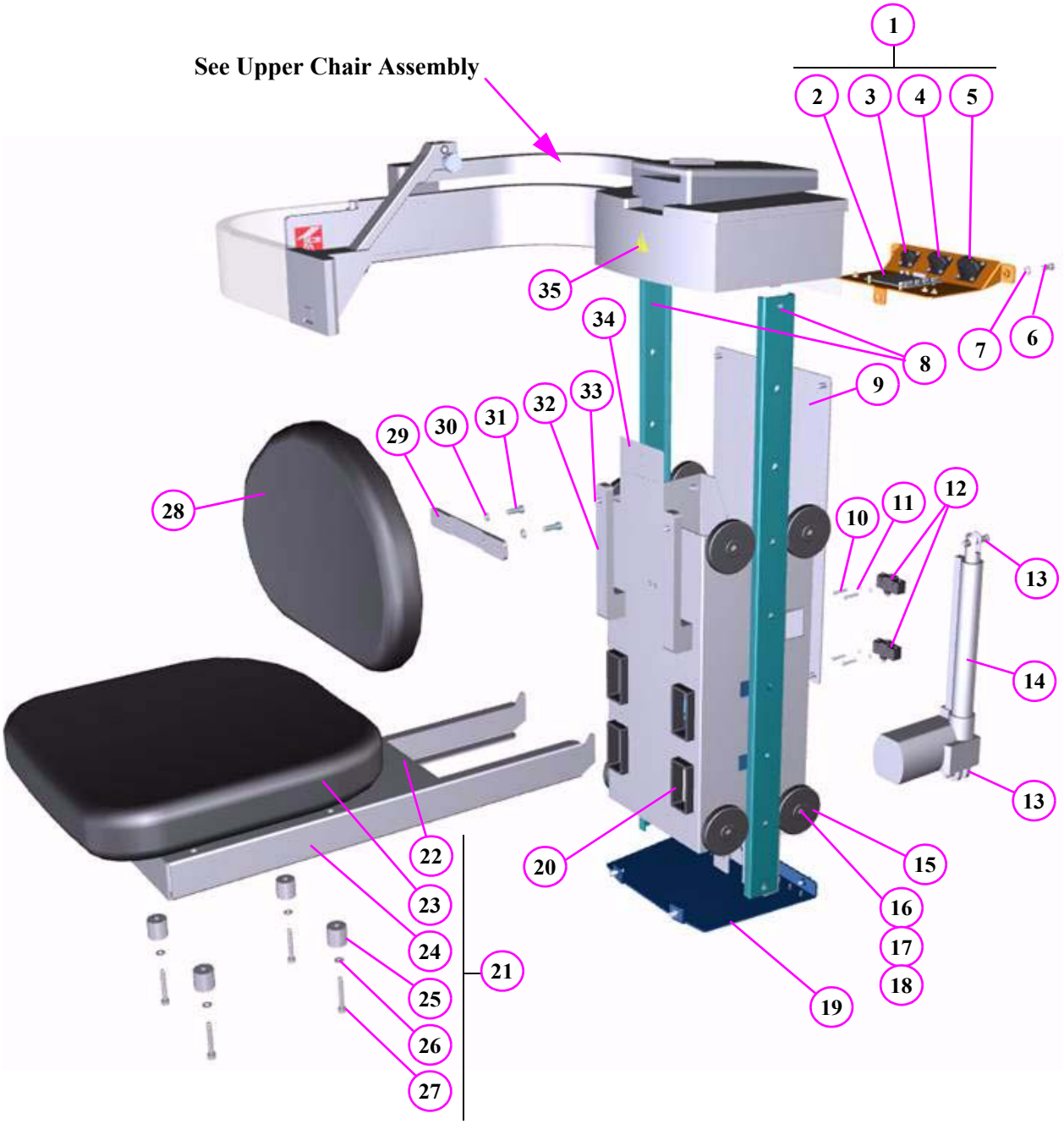
17-19 Flip Receptor Panel Assembly (133-0 or K133-0)



17-19 Flip Receptor Panel Assembly Parts List (133-0 or K133-0))

Item	ISI Part No.	KaVo Part No.	Description
1	133-14	K133-14	Panel Cover, Varian 2520D
2	800186	800186	Receptor Panel
3	133-2	133-2	Mounting Plate, Receptor 2520D
4			Flat Soc. Hd. M5
5	105-5-0	K105-5-0	Rear Receptor Cover Assy.
6	109-12	109-12	Stop Screw
7	109-0-2	109-0-2	Drive Screw Assembly
8			SHCS M3 x 8mm Long
9	109-2	109-2	Flip Stepper Motor
10	109-31	109-31	Idler
11	109-17	109-17	Cable Shield
12			Split Washer #10
13			SHCS #10-32 x 5/8 Long
14	1000189	1000189	Belt McMaster #6484K511
15	1585	1585	Receptor Fan Assembly
16	109-16	109-16	Belt Key
17			Flat Head Screw #8-32 x 3/8 Long
18	1550	1550	Flip Receptor Limit Switch Assembly
19			SHCS #4-40 x 5/8 Long
20			SHCS #10-32 x 3 1/2 Long

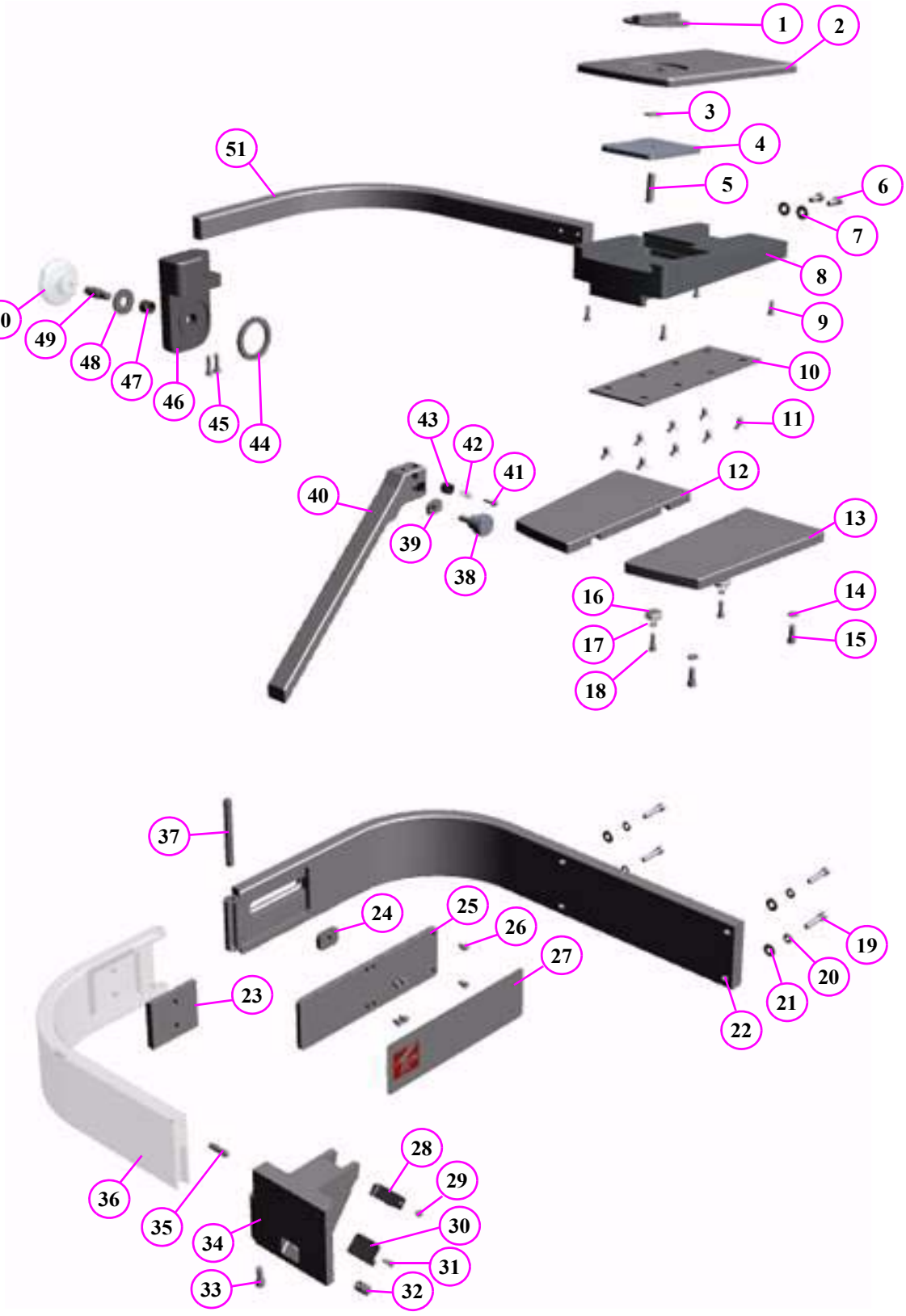
17-19 Chair Assembly



17-19 Chair Assembly Parts List

Item	ISI Part No.	KaVo Part No.	Description
1	1020-0	1020-0	Chair Receptacle Plate Assembly
2	1204	1204	Patient Alignment Board
3	1516	1516	Patient E-Stop External Cable
4			Wheel Chair External Cable (removed in later machines)
5	1522	1522	Chair Junction Cable
6			SHCS 1/4-20 x 5/8 Long
7			1/4 Split Washer
8	505-5	505-5	Rail
9	25-2	K25-2	Back Plate
10			SHCS #6-32 x 1 Long
11			#6 Split Washer
12			Wheel Chair Switch (removed in later machines)
13	1000029	1000029	McMASTER # 97245A688
14	1000028	1000028	MAGNETIC #ECO50-025MM1B0-000
15	23-1	23-1	Wheel
16	23-2	23-2	Wheel Axle
17			SHCS 1/4-20 x 1/2 Long
18			1/4 Split Washer
19	508-0	508-0	Actuator Plate
20	23-3	23-3	Receptacle Flange
21	21-0	G21-0	Seat Assembly
22	1309-3	1309-3	Chair Installation Label
23	1.009.2374	1.009.4972	Seat Pad, Bottom
24	21-2	21-2	Seat Frame
25	1000457	1000457	Plastic Spacers
26			M6 Split Washer
27			SHCS M6 x 45mm Long PHP ZN
28	1.009.2375	1.009.4974	Seat Pad, Back
29	23-6	23-6	Back Rest Adapter
30			1/4 Split Washer
31			SHCS M6 x 20mm Long
32	23-5	23-5	Seat Back Support
33			SHCS 1/.4-20 x 1/2 Long
34	1309-2	1309-2	Chair Warning Label 2
35	1309-1	1309-1	Chair Warning Label 1

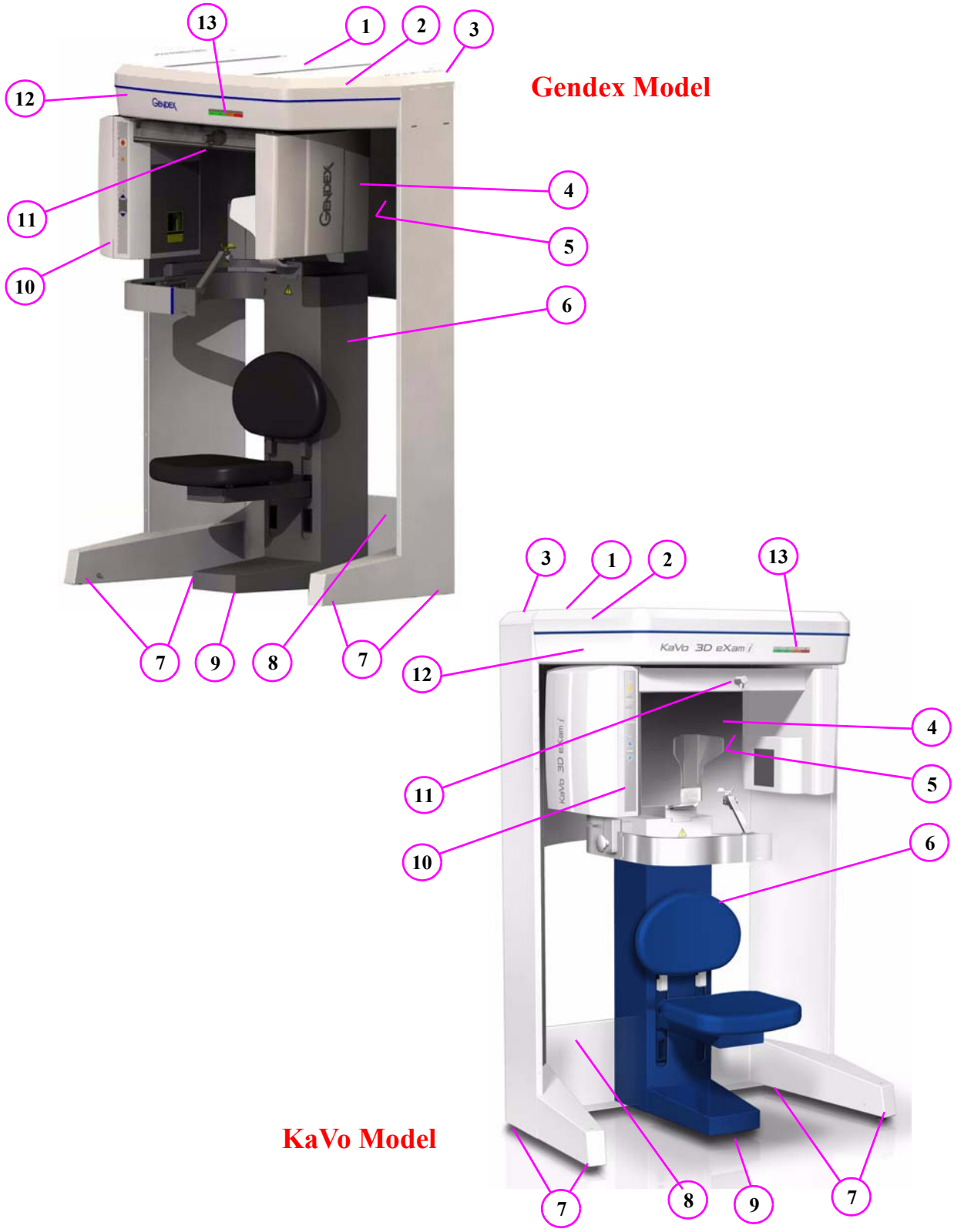
17-19 Upper Chair Assembly

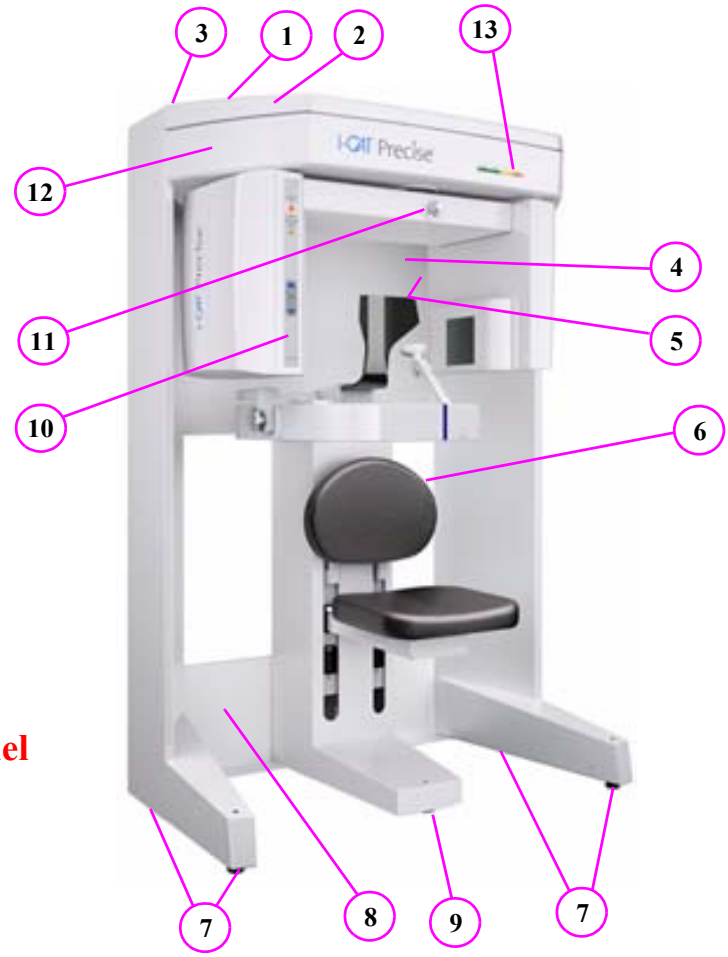


17-19 Upper Chair Assembly Parts List

Item	ISI/KaVo Part No.	Description
1	22-4	Clamp Knob
2	22-2	Support Plate
3		Nylon Flat Washer 5/16 ID - 3/4 OD
4	22-3	Clamp Plate
5		SS 5/16-18 x 1.25 Long
6		SHCS 1/4 - 20 x 5/8 Long
7		Flat Washer 1/4
8	22-1	Slider Block
9		SHCS #8-32 x 1/2 Long
10	22-10	Roller Plate
11		Flat Head 1/4-20 x 1/2 Long
12	22-5	Left Cap Plate
13	22-6	Right Cap Plate
14		Split Washer 1/4
15		SHCS 1/4-20 x 5/8 Long
16	240360	Dual-Vee #W1
17		Split Washer #10
18		SHCS #10-32 x 5/8 Long
19		SHCS 1/4-20 x 1 1/4 Long
20		Split Washer 1/4
21		Flat Washer 1/4
22	K24-1	Hinge Bar
23	1000045	Bunting #BM4071
24	24-4	Tee Nut
25	24-3	Magnet Plate
26		SHCS #10-24 x 1/4 Long
27	1314	Gate Label
28	26-11	Upper Guide
29		BHCS #6-32 x 1/4 Long
30	K26-10	Lower Guide
31		SHCS #6-32 x 1/2 Long
32	1000181	3/8 Spring Plunger McMaster Carr #8499A85
33		SHCS 1/4-20 x 5/8 Long
34	26-9	Slide Block
35		Dowel Pin 1/4 x 1 Long
36	K24-2	Gate
37	24-6	Gate Pivot Pin
38	26-4	Thumb Screw
39	26-3	Clamp Button
40	26-1	Chin Rest Guide
41		Shoulder Screw 1/8 Diameter x 5/16 Long x #4-40
42	310242	Century Spring #70464
43	26-2	Bite Tip Clamp Button
44	22-8	Glide
45		SHCS #10-32 x 3/4 Long
46	K22-11	Clamp Handle
47		Bronze Bushing .375 ID x .625 OD x .50 Long
48	22-12	Clamp Washer
49	22-9	Lock Shaft
50	1000047	J.W. Winko #6TCC3/E
51	K22-7	Arm

9-17 System Assembly



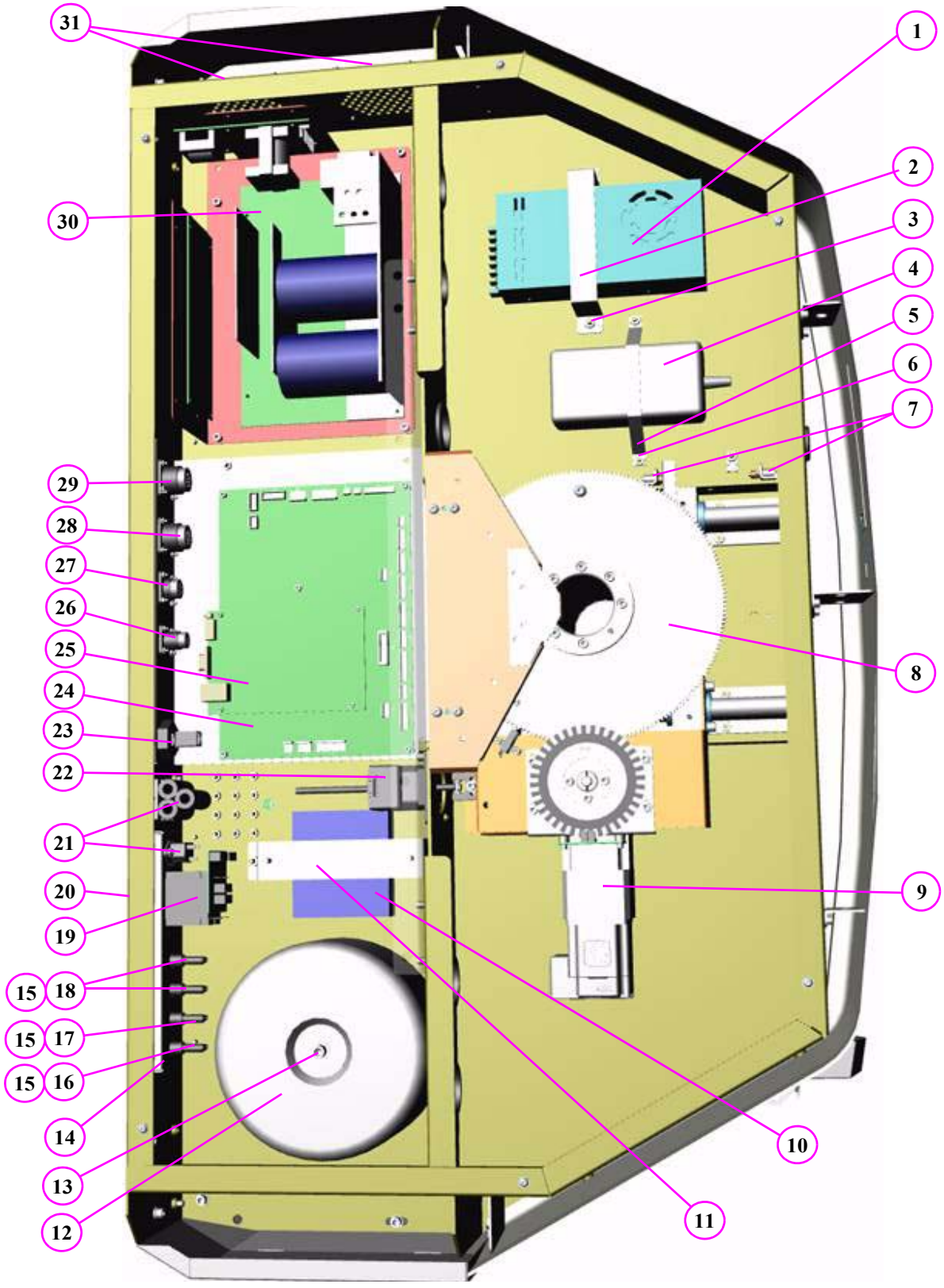


ISI Model

9-17 System Assembly Parts List

Item	Gendex Part No.	KaVo Part No.	ISI Part No.	Description
1	G150-4-0	G150-4-0	G150-4-0	Upper Cover
2				BHCS #8-32 x 3/8 Long
3	32-0	32-0	32-0	Wall Stabilizer (not shown)
4	G138-0	K138-0	1.008.8080	Flip Receptor Assembly
5	G101-7	K101-7	G101-7	Rear Scatter Shield
6	20-0	K20-0	20-0	Chair Assembly
7	1000031	1000031	1000031	IEC #IL8-6B x 3 HX-BC Bottom Chamfer
8	G534-0	G534-0	G534-0	Lower Plate Weldment
9	1000108	1000108	1000108	IEC #IL8-6B x 2 HX-BC Bottom Chamfer
10	G140-0	K140-0	1.008.8082	X-Ray Source Assembly
11	15-0	15-0	15-0	Laser Line Assembly
12	G150-3	K150-3	1.008.8091	Lower Cover
13	1302	K1302	1302	Resident Indicator Panel

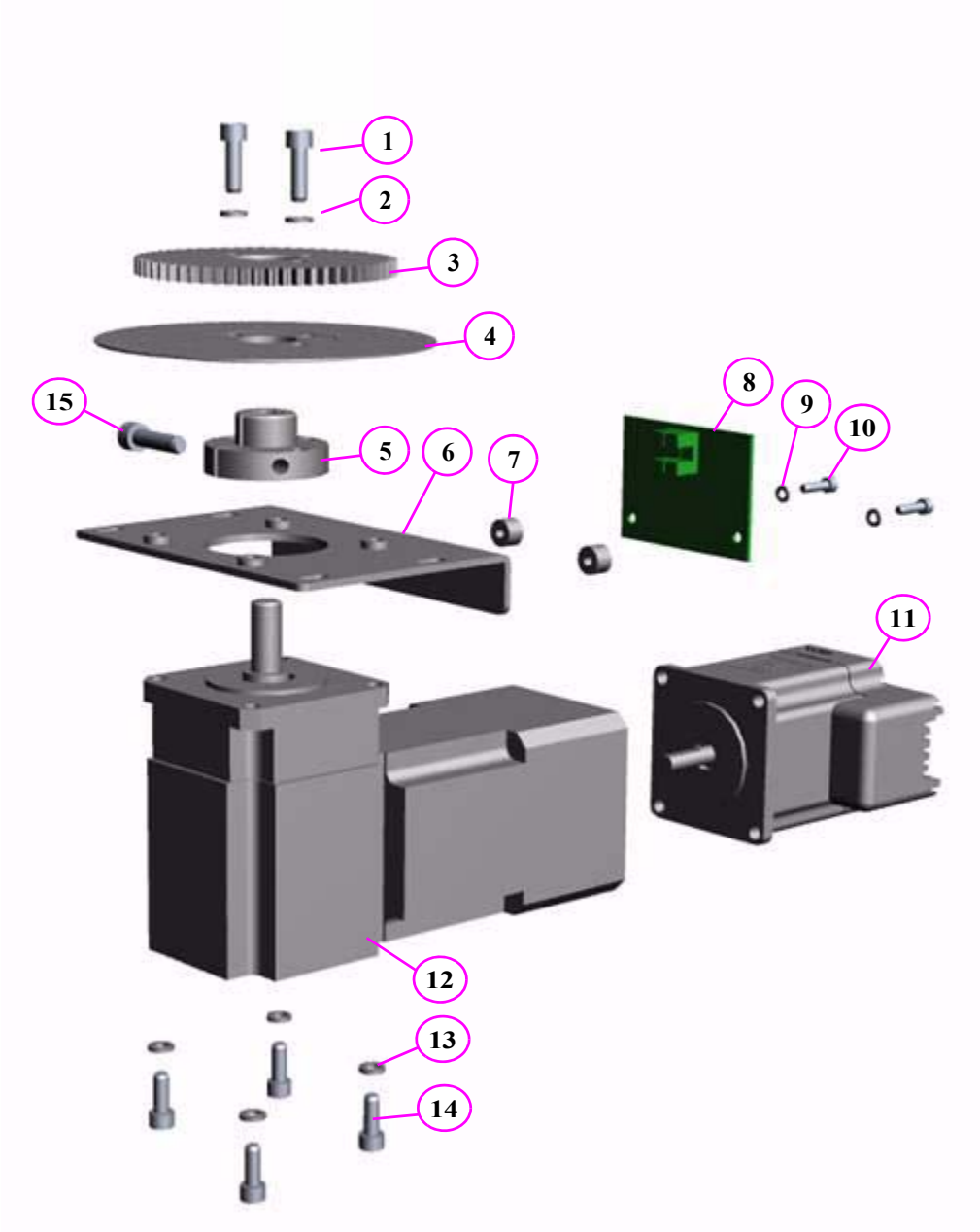
9-17 Overhead Assembly



9-17 Overhead Assembly Parts List

Item	Gendex/ISI/KaVo Part No.	Description
1	1000032	24V Power Supply
2	1000455	Hook and Loop Fastener
3		#10-32 Nut
4	1000236	Integrated Power Design (Receptor Power Supply)
5	1000455	Hook and Loop Fastener
6		#10-32 Nut
7	1507	Limit Switches (set)
8	9-0	Spindle Assembly
9	11-0	Rotation Drive
10	1025-0	Network Switch and Power Cable
11	1000455	Hook and Loop Fastener
12	1701-0	Toroid Isolation Transformer
13		SHCS 5/16-18 x 1 Long
14	K1015-0	Power Bracket Assembly
15	1000176	Buss #HTB-84M
16	1000010	10A Fuse Digi-Key #F985-ND
17	1000005	2.5A Fuse Digi-Key #F979-ND
18	1000011	1/4 A Fuse Digi-Key #F939-ND
19	1255	115VAC Circuit Breaker
	1256	230VAC Circuit Breaker
	1257	200VAC Circuit Breaker
	1258	100VAC Circuit Breaker
20	1310	Fuse Label (not shown)
21	1570	Line Choke
22	102-16	Stepper Motor Assembly - 17 Frame
23	1557	Ethernet Panel Mount Cable
24	1203	i-CAT System Board
25	1210	i-CAT Computer Board (Embedded Board)
26	1526	Warning System External Cable Assembly
27	1523	Door Interlock External Cable Assembly
28	1519	Control Box External Cable Assembly
29	1521	Chair External Cable Assembly
30	1000-0	X-Ray Power Supply
31	1541	Overhead Fan (pair)

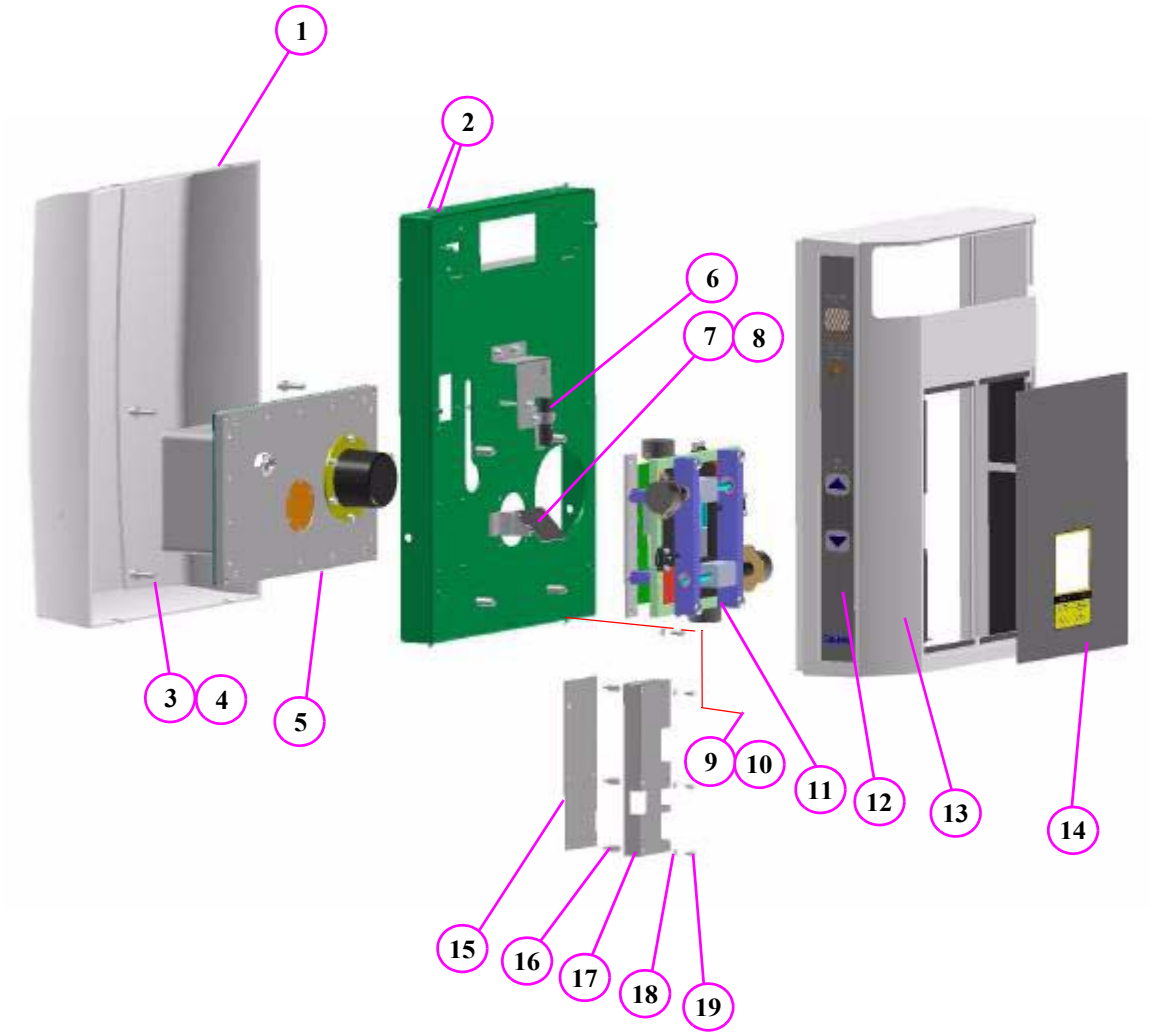
9-17 Rotation Drive Assembly



9-17 Rotation Drive Assembly Parts List

Item	Gendex/ISI/ KaVo Part No.	Description
1		SHCS #10-24 x 5/8 Long
2		Split Washer #10
3	11-5	Drive Gear
4	11-3	Gear Encoder Disk
5	11-4	Gear Clamp
6	11-2	Rotation Motor Bracket
7	1000027	Al. Round Spacer
8	1205	Gear Encoder
9		Split Washer #6
10		SHCS #6-32 x 1/2 Long
11	11-6	Stepper Motor
12	120110	Thomson Micron #NTR23-025
13		Split Washer #10
14		SHCS #10-24 x 1/2 Long
15		SHCS #10-24 x 3/4 Long

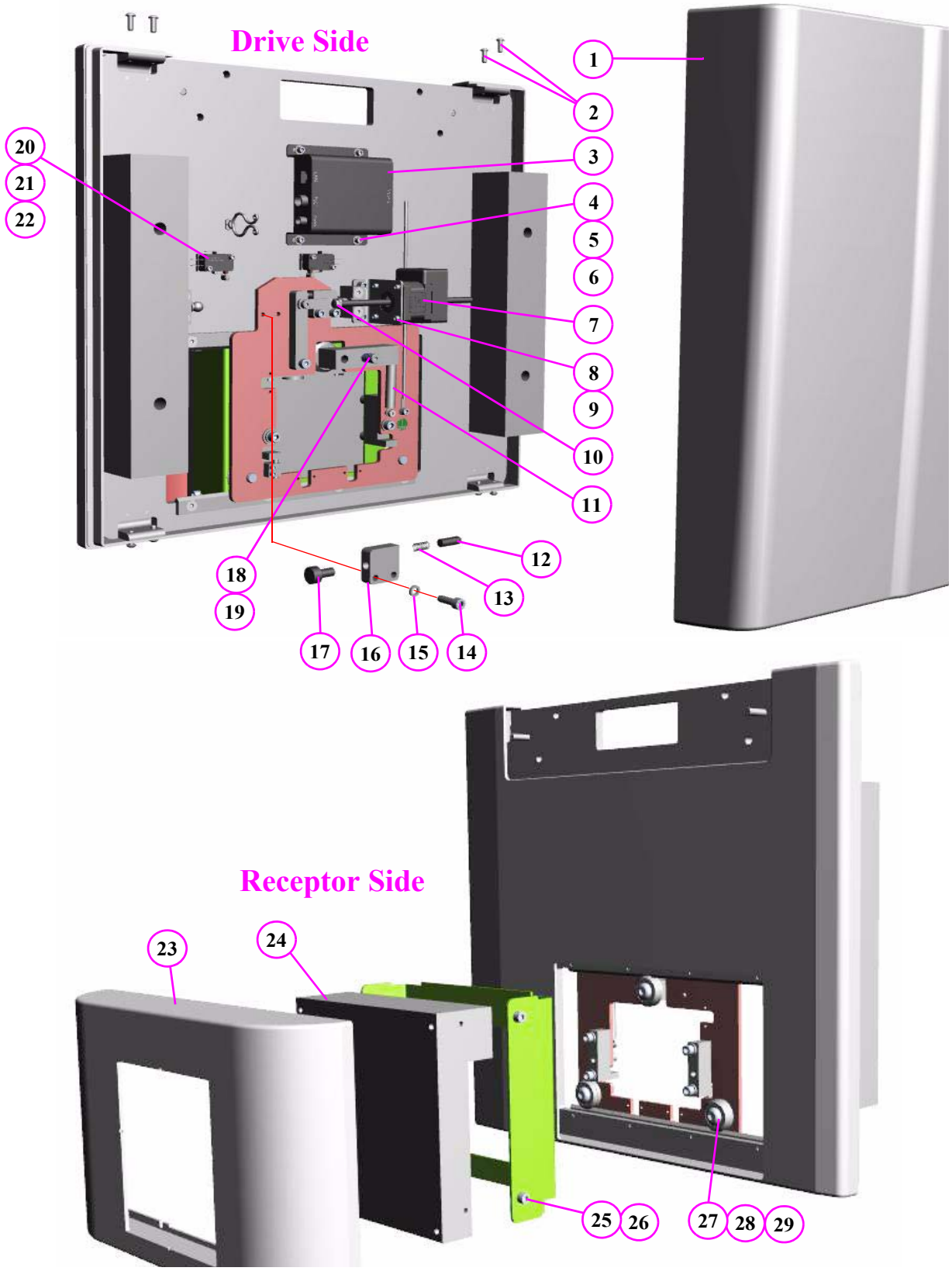
9-17 X-Ray Source Assembly



9-17 X-Ray Source Assembly Parts List

Item	Gendex Part No.	KaVo Part No.	ISI Part No.	Description
1	G140-7	K140-7	1.008.8090	Rear X-Ray Source Cover
2				BHCS #8-32 x 1/2 Long
3				SHCS 1/4-20 X 1 Long
4				Split Washer 1/4
5	35-0	35-0	35-0	Tube Head
6	16-0	16-0	16-0	Cross Laser Assembly
7	106-24	106-24	106-24	Cross Laser Mirror
8				BHCS #6-32 x 1/4 Long
9				Split Washer #10
10				SHCS #10-24 x 3/8 Long
11	147-0	147-0	147-0	Beam Limiter Asst
12	G1305	K1305	1305	Patient Alignment Panel
13	G140-2	K140-2-0	G140-2	Front X-Ray Source Cover
14	1308-0	1308-0	1308-0	Beam Limiter Panel
15	1206	1206	1206	Beam Limiter Control PCB
16	1000211	1000211	1000211	#6-32 x 1/2 Long Standoff McMaster #91
17	106-8	106-8	106-8	Beam Limiter Board Shield
18				Split Washer #6
19				SHCS #6-32 x 1/4 Long

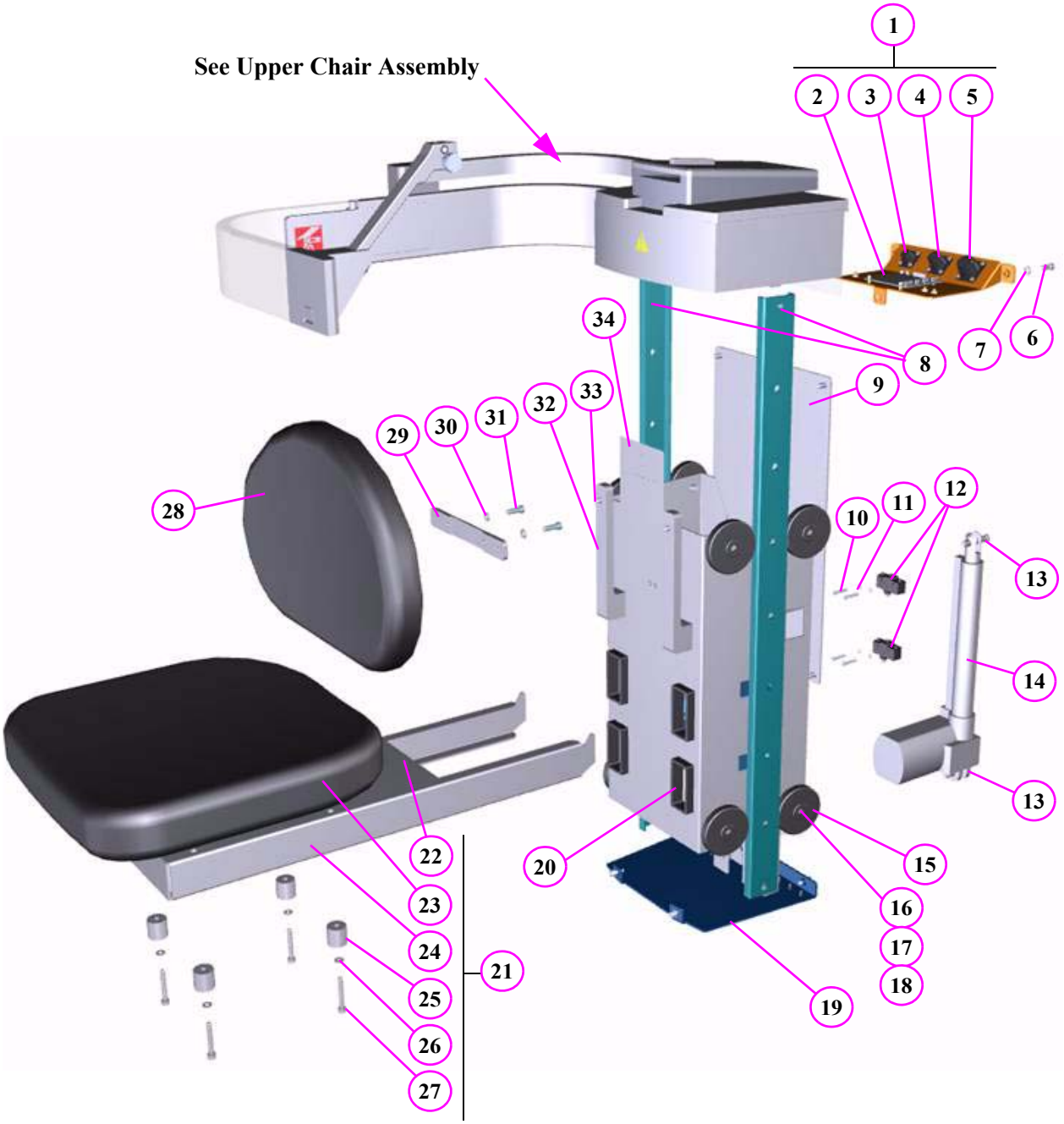
9-17 Receptor Panel Assembly



9-17 Receptor Panel Assembly Parts List

Item	Gendex Part No.	KaVo Part No.	ISI Part No.	Description
1	G138-20	K138-20	1.008.8081	Rear Cover
2				BHCS #8-32 x 1/2
3	1000237	1000237	1000237	Camera Card Pleora #PT1000-Cl4-E
4				SHCS #6-32 x 3/8 Long
5				Split Washer #6
6				Flat Washer #6
7	138-3	138-3	138-3	Shift Motor
8				SHCS M3 x 8mm Long
9				Split Washer M3
10				Nut #8-32 (shift motor)
11	1000259	1000259	1000259	Spring McMaster #94135K13
12	138-11	138-11	138-11	Plunger
13	310243	310243	310243	Century Spring #70602
14				SHCS #10-32 x 5/8 Long
15				Split Washer #10
16	138-10	138-10	138-10	Plunger Block
17	1000188	1000188	1000188	McMaster # 8511A24
18				Shoulder Screw 1/4 Diameter x 1 1/4 Long x #10-32
19	1000257	1000257	1000257	Century Spring #71126
20	1550	1550	1550	Flip Receptor Limit Switch
21				SHCS #4-40 x 3/4 Long
22				Split Washer #4
23	G138-18	G138-18	G138-18	Panel Cover
24	800170 or 800172	800170 or 800172	800172	1313 Receptor
25				SHCS M5 x 10mm
26				Split Washer M5
27				BHCS 3/8-16 x 3/4
28	240361	240361	240361	Dual Vee #W2
29				Shim Washer 3/8 ID x .02 Thick

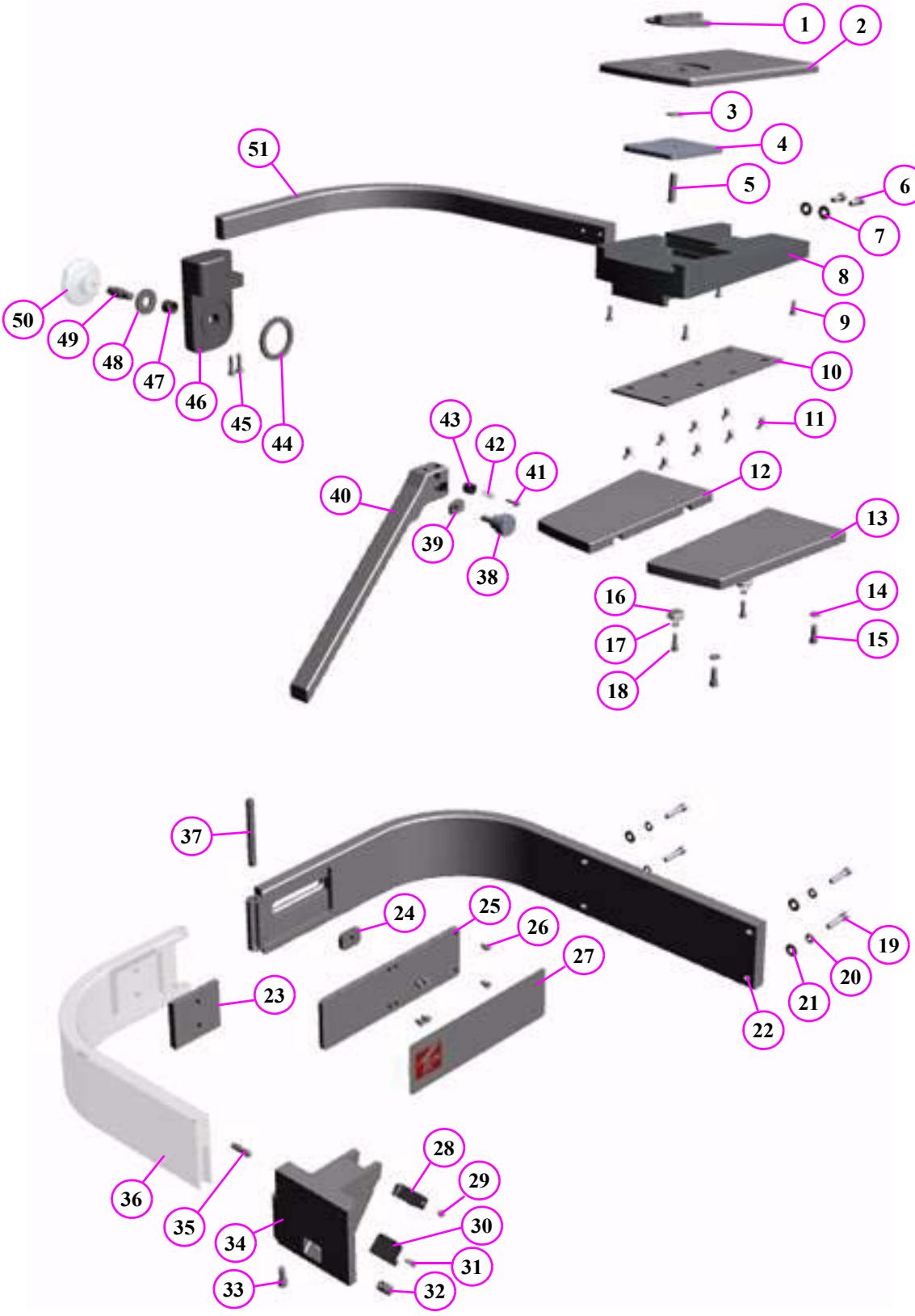
9-17 Chair Assembly



9-17 Chair Assembly Parts List

Item	Gendex Part No.	KaVo Part No.	ISI Part No.	Description
1	1020-0	1020-0	1020-0	Chair Receptacle Plate Assembly
2	1204	1204	1204	Patient Alignment Board
3	1516	1516	1516	Patient E-Stop External Cable
4				Wheel Chair External Cable (removed from later machines)
5	1522	1522	1522	Chair Junction Cable
6				SHCS 1/4-20 x 5/8 Long
7				1/4 Split Washer
8	505-5	505-5	505-5	Rail
9	K25-2	K25-2	K25-2	Back Plate
10				SHCS #6-32 x 1 Long
11				#6 Split Washer
12				Wheel Chair Switch (removed from later machines)
13	1000029	1000029	1000029	McMASTER # 97245A688
14	1000028	1000028	1000028	MAGNETIC #ECO50-025MM1B0-000
15	23-1	23-1	23-1	Wheel
16	23-2	23-2	23-2	Wheel Axle
17				SHCS 1/4-20 x 1/2 Long
18				1/4 Split Washer
19	508-0	508-0	508-0	Actuator Plate
20	23-3	23-3	23-3	Receptacle Flange
21	21-0	G21-0	21-0	Seat Assembly
22	1309-3	1309-3	1309-3	Chair Installation Label
23	1.009.2374	1.009.4972	1.009.2374	Seat Pad, Bottom
24	21-2	21-2	21-2	Seat Frame
25	1000457	1000457	1000457	Plastic Spacer
26				M6 Split Washer
27				M6 x 45mm Long PHP Zn
28	1.009.2375	1.009.4974	1.009.2375	Seat Pad, Back
29	23-6	23-6	23-6	Back Rest Adapter
30				1/4 Split Washer
31				SHCS M6 x 20mm Long
32	23-5	23-5	23-5	Seat Back Support
33				SHCS 1/.4-20 x 1/2 Long
34	1309-2	1309-2	1309-2	Chair Warning Label 2

9-17 Upper Chair Assembly



9-17 Upper Chair Assembly Parts List

Item	Gendex/ISI/KaVo Part No.	Description
1	22-4	Clamp Knob
2	22-2	Support Plate
3		Nylon Flat Washer 5/16 ID - 3/4 OD
4	22-3	Clamp Plate
5		SS 5/16-18 x 1.25 Long
6		SHCS 1/4 - 20 x 5/8 Long
7		Flat Washer 1/4
8	22-1	Slider Block
9		SHCS #8-32 x 1/2 Long
10	22-10	Roller Plate
11		Flat Head 1/4-20 x 1/2 Long
12	22-5	Left Cap Plate
13	22-6	Right Cap Plate
14		Split Washer 1/4
15		SHCS 1/4-20 x 5/8 Long
16	240360	Dual-Vee #W1
17		Split Washer #10
18		SHCS #10-32 x 5/8 Long
19		SHCS 1/4-20 x 1 1/4 Long
20		Split Washer 1/4
21		Flat Washer 1/4
22	K24-1	Hinge Bar
23	1000045	Bunting #BM4071
24	24-4	Tee Nut
25	24-3	Magnet Plate
26		SHCS #10-24 x 1/4 Long
27	1314	Gate Label
28	26-11	Upper Guide
29		BHCS #6-32 x 1/4 Long
30	26-10	Lower Guide
31		SHCS #6-32 x 1/2 Long
32	1000181	3/8 Spring Plunger McMaster Carr #8499A85
33		SHCS 1/4-20 x 5/8 Long
34	K26-9	Slide Block
35		Dowel Pin 1/4 x 1 Long
36	K24-2	Gate
37	24-6	Gate Pivot Pin
38	26-4	Thumb Screw
39	26-3	Clamp Button
40	26-1	Chin Rest Guide
41		Shoulder Screw 1/8 Diameter x 5/16 Long x #4-40
42	310242	Century Spring #70464
43	26-2	Bite Tip Clamp Button
44	22-8	Glide
45		SHCS #10-32 x 3/4 Long
46	K22-11	Clamp Handle
47		Bronze Bushing .375 ID x .625 OD x .50 Long
48	22-12	Clamp Washer
49	22-9	Lock Shaft
50	1000047	J.W. Winko #6TCC3/E
51	K22-7	Arm

Chapter 4 IEC IC Command Codes

Home Commands

HB Home Beam Limiter
(HB = 0, 0, 0, 0 All four shutters completely open)

HFR Homes gantry and sets position to 100000

HP Homes gantry and sets position to 1500

HSR Quick home check if the machine is already homed

Movement Commands

MB Move Beam Limiter right left top bottom
Enter command as **MB** X X X X where X is:
(right left and bottom shutters range: 0 – 2600)
(top shutter range: 0 – 3300)

Example: MB 700 700 3000 1500

MP Move Platform [target] [speed]
Enter command as **MP** X X where X is:
(target range: 1500 – 100000, speed range: 1000 – 54000)

Example: MP 1500 1500

MPM Target Speed.
Enter command as **MPM** X X where X is:
Target or Position: between 0 - 90 mm (home position is zero - absolute)
Speed: between 1000-54000

Example: MPM 20 1500

MPP Position type, moves receptor panel's position.
Enter command as **MPP** X X where X is:
Position: 0 or 1 (Landscape or Portrait/Halfbeam)
Type: 0 or 1 (Platinum or Nano)
Example: MPP 1 0

MR Target Speed.
Enter command as **MR** X X where X is:
Target: between 35000 - 733333
Speed: between 1000 - 65000

Example: MR 35000 1000

MRD Target Speed.
Enter command as **MRD** X X where X is:
Target: between -40 - 430 degrees (home position is equal to zero degrees - absolute)
Type: between 1000 - 65000

Example: MRD 180 1000

Read Commands

RB Read beam position
returns right left top bottom shutter positions

RD Read Door Status: 1 -Open and 0 -Closed

RE Read Exception Register

Exceptions

1 Emergency Stop activated
2 Stall Detected
4 X-ray Tube Short
8 X-ray Watchdog Timeout
16 Linux Watchdog Error
32 X-ray Fault from X-ray Controller
64 Platform needs to be Homed
128 Rotation needs to be Homed
256 Beam Limiter Not Initialized
512 Machine is Turned Off
1024 Door Interlock was Opened During an X-ray Exposure
2048 Ethernet Cable Communication Failed During an X-ray Exposure
4096 The Panel Position error - both limit switches are reading high or low

RI Read Input Register to the RI

Read Input Command - returns the 21 bit input register with the following definition:

1 Emergency Stop
2 Machine On Switch
4 Machine Off Switch
8 Scan Enable Button Status
16 Error from X-ray Controller
32 Encoder Direction
64 Rotation Optical Switch Status
128 Rotation Limit Switch
256 Rotation Start of Travel Status
512 Rotation End of Travel Status
1024 Platform Start of Travel Status
2048 Platform End of Travel Status
4096 Door Signal
8192 Panel Horizontal (Landscape)
16384 Panel Vertical (Portrait)
32768 Machine Power Status
65536 Right Shutter Limit Switch
131072 Left Shutter Limit Switch
262144 Top Shutter Limit Switch
524288 Bottom Shutter Limit Switch
1048576 Moving Signal for Panel Flip Motion
2097152 Moving Signal for Rotation Motion
4194304 Moving Signal for Platform Motion

RMS Read usage time of selected item
Returns xxxxdxxhxxmxxs

0 Beam Limiter Motors
1 Embedded Board
2 Panel
3 Platform Motor
4 24V Power Supply
5 Rotation Motor
6 X-ray
7 Flipper Motor

RP Read Platform position

RPP Read Panel Position

- **0** Error
- **1** Landscape mode
- **2** Portrait mode
- **3** Error

RR Read Rotation position.

RX Read X-ray Setup
See SX command for argument description.
0 = 120KV Range **1** = 90 KV Range
If no parameter is entered, then the command assumes 0.

SP Sets platform position - Sets the counts of the platform.
Must be less than 65000.

SR Sets rotation position - Sets the counts of the rotation.
Must be less than 733333.

SX Set X-ray
kvp, ma, frame rate, xrayon, xrayoff, panel readout, panel_mode
Enter command as **SX** X1 X2 X3 X4 X5 X6 X7 X8 where X is:
X1 specifies kV = 80 - 126 in increments of 2 only.
X2 specifies mA = 0-2. 0=3mA, 1=5mA, 2=7mA
X3 specifies frame rate = in between 50000000 - 833333 => 50 MHz/frame rate (1-60 frames/sec)
X4 specifies X-ray on = typically set to 1 and between 0 - (frame rate - 1)
X5 specifies X-ray off => greater than X-ray on and less than (frame rate - 1) 5000 =1 msec (set as needed for desired length)
X6 specifies Panel Readout = Typically set the same as the X-ray off (except for continuous X-ray mode) in between 0 - (frame rate - 1)
X7 specifies Panel Pulse mode (0 or 1) (if not entered, defaults to 0).
0 - 20 microsecond pulse for panel readout and valid frame.
1 - either a 5msec pulse for valid frame or 3msec for panel readout
X8 specifies the tube 0 = 120 KV tube, 1 = 90 KV tube
Example: SX 120 1 3333333 1 780000 780000 0
If X7 and X8 are not specified, both are assumed to be zero.

X-Ray Commands

XP Frames
Maximum limit capped by the 44 second x-ray watchdog
Number of frames: 1 - 1024
Ethernet Watchdog 0 = disabled, 1 = enabled
(Number of frames*Frame Rate) <44 seconds

Miscellaneous Commands

GS Read System Information
Machine Version, Hardware Version, Software Version
Beam Limiter Version, Machine Serial Number

CS Cancel Scan.
Cancels a scan.

CE Clear Exception Register.
Clears all exceptions except for error that require initialization.

WSB Enable Scan Button.
Enables the scan button to initiate a scan.

Chapter 5 VisionQ/Vision Release Notes

New Features for 1.9.3
Added DAP information to scan parameters dialog, which is displayed prior to the scan.
Preview images are automatically saved as part of the patient's dataset.
InVivo application can be launched from Vision without first loading a study.
Vision standalone is now supported in Windows 7 Professional or Ultimate (32-bit or 64-bit modes).

New Features for 1.9.2
Vision software translated into Turkish, Chinese, and Russian and new 1.9 features available in all supported languages.

New Features for 1.9.1
Added study progress indicators to the Patient Study List which show whether a study is acquiring, reconstructing, transferring, or ready for viewing.
Added a Quantum IQ tag to studies on the Patient Study List that have the Quantum IQ filter applied.
Added a rotation tag to studies on the Patient Study List that have been volume rotated and reimported into the Patient Database.
Added feature to import a study into the Patient Database.
Added feature to rescan and update the Patient Database.
Added feature to designate a "Fast" computer as the master of the Patient Database.
Added feature to support DICOM Storage Commitment on a separate connection in RSSM.
Moved option to turn on/off DICOM Auto Send to the main Tools - Settings menu.

Added feature to export a rotated CT volume in DICOM format, and optionally reimport it into the Patient Database.
Added feature to launch Dolphin 3D™ software with the current study.
Added Dose Area Product (DAP) support for Sweden and the Netherlands.
Added CT custom collimation protocols to systems with Dose Area Product (DAP) enabled.

New Features for 1.9.0
Added Quantum IQ™ feature which smoothes out the noise in the soft tissue of CT images while preserving the detail in bone and other hard materials.
Added support for SureSmile customers by improving the HU and Spatial resolution of CT images.
Added features to support Dose Area Product (DAP) compliance.
Added DICOM Little Endian Implicit Transfer Syntax support for sending/receiving reconstructed CT and PAN DICOM files to/from a DICOM PACS server.
Added feature to automatically send reconstructed iPAN images to a DICOM PACS server.

New Features for 1.8.1
Added support for Cesium detector panel on GXCB-500, and 3D eXam *i* scanners.
Added features to allow compliance testing for DIN-standards for iPan mode in Germany.
Added support for multi-byte languages, allowing support for Japanese and Korean language translations of the software. This feature also adds support for patient and referring physician names with multiple representations (single-byte, ideographic, and phonetic representations). Dutch, Polish, and Czech language translations were also added.

ID	Resolved Issues in 1.9.3
1430	DAP measurements refined for 6cm protocols on MFOV.
1431	Patient list entries are no longer duplicated when DOB not provided with patient information via PM/Worklist.
1439	German translations corrected in Setup screen.
1444	When attempting to load an invalid dataset, the user is notified and the application exits.
1450	Patient study access time upon startup is much improved due to better sorting algorithms.
1452	Erroneous reporting of firmware version verification failures has been corrected.
1453	Patient study visibility corrected for overnight VisionQ application runs.
1454	HU baseline data for MFOV Cesium panels has been improved.

ID	Resolved Issues in 1.9.2
1362	Numerous Japanese-language errors have been corrected.
1380	The Contour line Setup Dialog (Maxilla or Mandible option) will no longer appear multiple times when the automatic arch feature fails for either of the arches.
1410	New installs of acquisition software no longer display a warning message regarding modification of iCATSystem.xml file on first run.
1414	Database rebuilds initiated during software upgrades will not encounter insufficient-memory errors under normal conditions. Large database may be upgraded without the need to restart the software.
1415	Systems employing backup software which sets the Archive attribute on files and folders will no longer interfere with display of new patients and scans.
1417	Interrupted scans will no longer result in the possible reconstruction of scan-data from previous scans. This problem could have resulted in corrupted images or images corresponding to different patients.
1418	Collimation shutter positions will now be correct when using custom collimation protocols saved as Quick Picks.
1419	CT studies containing invalid data will be displayed in the study-list after an upgrade, but attempts to open one of these studies will result in an error message displayed to the user, and the study will not be loaded.

ID	Resolved Issues in 1.9.2
1425	Corrected vertical field-of-view size for 6 cm scan protocols on GXCB-500 and 3DeXam i systems, which were resulting in 8 cm previews and raw-data.
1426	Retro-reconstruction will no longer result in intermittent failure to display preview images with loss of QF Toggle functionality after loading raw data.

ID	Resolved Issues in 1.9.1
593	Patients with same Patient ID but differing names or birth dates will now be displayed on the Patient List as separate patients, and only the studies corresponding to the selected patient will be shown on the Study List.
753	HU values on Half-Beam and Laterally Collimated scans are now more accurate.
1028	JPEG and TIF images for Reconstruct PAN images are now exported to the correct folder.
1098	Crashes and other abnormal behavior during update of the Patient List have been corrected.
1105	DICOM Storage Commitment now works on a separate connection in RSSM.
1110	Factor of 2 error in HU values on Half-Beam and Laterally Collimated scans has been corrected.
1117	Crashes when loading DICOM file with empty pixel spacing in tag (0028,0030) has been corrected.
1158	The TMJ axial image no longer gets magnified when using "Fit To Window" on reports.
1163	High resolution/large volume custom collimation CT scan vertical collimation settings are now limited to prevent out of memory conditions.
1226	An issue where blank images are printed to pdf files from reports has been corrected.
1256	Exporting of a 0.125mm CT scan as a single uncompressed DICOM file now functions properly.
1273	Sure Smile customers are supported in this software release.
1279	Retro-reconstruction of landscape scans now lists the proper allowable reconstruction protocols.
1287	MFOV Roll-Off correction values are now correct for the HU QA test.
1308	Measurements on the Implant Screen no longer shift vertically in Reports for LFOV Portrait (17cm) scans.
1311	The blue vertical cross-section lines representing condyle positions on the TMJ screen are now positioned correctly in Reports.

ID	Resolved Issues in 1.9.1
1316	The tick annotation on report images generated from the Axial Image on the Implant screen is now sized to minimize covering of anatomy.
1320	The slice location tag in DICOM files for the 0.125 resolution CT scans now contains the correct value.
1321	The image matrix size for MFOV 8.5cm custom protocols now matches the corresponding standard protocols.
1330	MFOV 14cm diameter custom 6.6cm CT scan reconstructions no longer fail.
1337	Sorting by Referring Physician on the DICOM Modality Worklist Screen in RSQM now works properly.
1338	The Station Name is now retrieved from a DICOM Modality Worklist SCP.
1340	Factory Quick Picks can no longer be deleted on non-English systems.
1348	The speed search text box in the Select Patient Dialog is now always positioned within the screen.
1352	Proper preview scans are now displayed on the Acquisition/ Reconstruction Screen after initiating a CT retro-reconstruction.
1354	Cancelling a Tru-PAN rendering followed by cancelling the Select Panoramic Method Dialog no longer confines the user to the Preview Screen.
1355	Exporting data using the single file selection now preserves proper HU values.
1359	Datasets retrieved from GE PACS servers that are adding the sequence to private tag (7fe0,0010) can now be read.
1360	A crash in RSQM has been fixed by no longer allowing the user to retrieve a study while another study is being retrieved.
1370	Image quality for retro-reconstructions has been improved by using the Air Cal value from the original study if it is available, rather than using the current Air Cal value from the scanner.
1373	Arches are no longer recomputed when an Implant screen rotation is performed followed by a switch to the Preview Screen.
1374	Rotations on the MPR screen are now maintained in workups.
1378	A crash during rotation of the panoramic image on the Implant Screen has been fixed.
1388	Adding a BMP or JPEG image to a Report no longer causes an application crash.
1395	InVivo launching now works on non-English and 64-bit OS systems.
1408	Switching between preview screens during an acquisition now behaves properly and no longer causes an application crash.

ID	Known Issues
113	On Implant screen, pressing Alt-F4 does not return to Preview Screen as with TMJ, Ceph, MPR screens.
150	Using the right-click shortcut does not show the Workup menu selection after a scan has been taken.
158	Wrong message displays during Geo Cal. Message “Preparing Geocalibrate preview acquisition” should display instead of “Moving panel to Landscape”.
177	In Reports, changing the size of Image (when Clip option is selected) displays the ruler at wrong position.
225	GXCB-500 Only: Collimation Calibration GUI in Calibrate.exe uses Portrait, Landscape terminology.
230	E-stop button needs to be released to stop multiple dialogs from displaying. Workaround: User must obey the message “E-stop is pressed” dialog box and lift the E-Stop button when trying to enter Acquisition screen.
239	Stopping Geo Cal closes Calibration application. Workaround: Restart Calibration application.
273	iPAN slide bar covering only 980 frames from 1276.
288	Sometimes after burning a CD (single-uncompressed format) with a workup saved, when loading the CD, the workup name appears as NO NAME.
293	Performing a second Geo Cal after a successful first test causes problem. Shutter location not calculated correctly for customizations and defaults are not remembered for Landscape and Portrait Geo Cal. Workaround: Restart the Calibration application to resolve problem.
316	Filter Settings “Reset to Default” fails to reset default setting although right-click check indicates default settings.
372	3DVR crashes when dragging the slider bar in the Range 4 section when using the Identify feature in Ax Views.
380	Level Up option under top menu has been changed. Related to FR-0256. Workaround: Use Screen menu option.
382	GXCB-500 Only: When user goes into the estimate nerve canal feature and confirms canal, if user changes the default matrix size from 5x2 to be either 3x1 or 7x3, errors are displayed.
392	Export CD: CD creation fails when selecting Multi-File DICOM.

ID	Known Issues
394	Export CD: The data size estimate is identical for compressed and uncompressed. The “Total to Write” size is not accurate when the uncompressed option is selected.
396	When removing data outside of scanfield, 5 to 6 mm of data is removed.
413	3DVR application: Error message displays after a second data set is opened when a Calculate VRT is performed.
422	When opening the Implant view, part of the axial image is outside the edge of the view.
481	Reports: No print preview option. Relates to FR-0541.
482	Reports: Undo option is grayed out. Relates to FR-0546.
489	In Reports, missing landscape template containing Panoramic data only. Related to FR-0388.
491	GXCB-500 Only. In Reports, variables in a template need to be added in separate boxes in order to be updated properly from case to case, when using the same template for different cases.
496	PAN: Method to lock bite stick vertically does not exist.
523	Previewing continuously within the Calibration application causes the image to flicker between last preview and current one.
527	Chair alignment inaccurate in field. Workaround: Align the placement of the chair using the calibration procedure and the Chair Alignment functionality in the Calibration application.
534	GXCB-500 Only: When capturing a PAN scan, if e-stop button is pressed, incorrect dialog is displayed instructing to “Close door to continue scan message”. If Retry is selected on dialog, application stays in a loop. Workaround: User needs to click on Cancel to clear exception and have proper message displayed related to e-stop button pressed.
540	When autodetecting arches, infrequently blue dots appear but not green line.
543	GXCB-500 Only: New scan is not highlighted after a scan has been taken. The previous loaded CT is highlighted.
547	GXCB-500 Only: VisionQ application does not respond if an implant template is loaded using a lower matrix.
550	GXCB-500 Only: High Resolution Half Scans. Acquisition screen displays a black frame when adjusting W/L during the reconstruction process.
553	GXCB-500 Only: Preview Screen. Coronal view changes from RAD to MIP if user enters Ceph Screen, and then returns to Preview screen.

ID	Known Issues
578	GXCB-500 Only: Preview Screen. Axial view RAD projection changes to MIP when moving the height of any arch.
583	GXCB-500 Only: Volume center stays in the Back position for CT, instead of the last position it was set to, when going from iPAN to CT mode.
593	Patient List: If data and/or images are moved from one system to another and the patient ID collides with an existing patient, the new data and/or images will be included in the existing patient's Patient List entry. However, the patient information displayed in the Vision window and any reports generated will be correct since that information is taken directly from the DICOM fields in the files, not the Patient List. Finding the newly added patient under these circumstances can be difficult, since it will appear under the original patient's name.
600	GXCB-500 Only: 3D airway image should display the proper cursor to move image. Zoom, W/L and Pan do not apply.
605	MF and BD display previous loaded CT values when a new scan has been taken. Workaround: Change to the desired Display Format prior to performing the Nerve Canal estimation.
606	Report: An empty Report folder gets created in the path where an iPAN jpeg is saved.
611	Recon BACK_PRJ crash when using two monitors on ACQ. Workaround: Do not use a second monitor on the VisionQ system.
615	Reports: Saved report contains stray characters and missing/misaligned text.
618	Vertical lines displayed in cross-section view of Implant screen.
624	Some viewing parameters are not retained when exiting and re-entering sub-screens.
640	TMJ report does not retain sizing when reopened.
651	GXCB-500 Only: After nerve canal detection, when ST < = 1.0mm on, panoramic arch gets out of place when moving the diagonal control to move arch to see the canal. Workaround: Adjust arch in main Preview window.
661	Incorrect display and crash using reports. Workaround: Select 20 or fewer description / options when adding text to a report.
664	Nerve canal error with a missing link.
668	Interpolation / filtering is not applied automatically when using mouse to scroll through slices in MPR screen.

ID	Known Issues
682	Nerve Canal question screen text appears when any pervious nerve canal has been done on the dataset. Workaround: Select Yes to remove previous nerve canal detection.
685	Control panel X-ray ready light not in sync with popup window “Push scan button”. Workaround: Wait for popup window prior to pressing scan button for X-ray ready light.
693	GXCB-500 Only: Preview image does not refresh after the E-stop / Door software has been activated during a CT scan.
700	Report/volume slice mapping not unambiguously possible, especially left/right determination.
703	Calibration: Chair alignment feature should work with the platform (panel) set only at home position. Workaround: Move the platform (panel) all the way to the back (home) position prior to performing the chair calibration.
737	Reports: Out of Memory exception on JPEG export.
753	Hounsfield values will not be correct for new 17-19 8x8 protocol released in both iCAT and 3DeXam. HU values will be too low (attributable to bilateral truncation effects).
879	Attempting to run Calibration when there is no network connectivity to the scanner, or the device ID is powered-off, will result in an error message displayed to the user that the device is not powered-on. After dismissing this message, the Calibration application appears to have quit, but is actually still running with no visible indication. Attempting to run Calibration again will result in the error message "Only one instance can be run". Workaround: Use task manager to force the hidden instance to quit, or restart the Acquisition PC to clear this condition.
962	The Distance measurement tool is not as responsive when used on the cross-section views of the Implant screen. Workaround: The mouse button must be held for at least one second before the distance line will be displayed and begin tracking with mouse-movement. Releasing the mouse-button in less than one second will result in a zero-length distance measurement, regardless of mouse-movement.
967	The Vision and VisionQ applications may crash when attempting to rotate the axial image in the Implant screen for portrait-mode scans. Workaround: Adjust the rotation of the axial view in the Preview screen before opening the Implant screen.

ID	Known Issues
981	Vision standalone is not compatible with LegacyExporter.msi. 1.7.x software is not compatible with previously released Legacy Exporter plugins. Attempting to use a pre-1.7 Legacy Exporter plugin will result in an invalid menu entry in the plugins menu, displaying square-box characters. Workaround: Contact Technical Support to obtain a new Legacy Exporter plugin for 1.7 software.
996	CD Export: Output to folder duplicates slice offset value. Accessing data files for an existing study is not safe while a CD-export operation is in-progress. This may result in the existence of files with the extension DCM2 left in the study directory. Workaround: Do not access study data files using any software other than the instance of iCATVision/iCATVisionQ performing the export until the CD-export has completed.
1011	iCATVision Implant screen: when cross section is zoomed IN measurements or nerve canal trace don't get displayed on cross section when saving as jpeg. Measurement and nerve-canal overlays are not properly displayed in JPEG images saved from zoomed cross-section views in the Implant screen. Workaround: Use the corresponding un-zoomed cross section image to create JPEG images.
1060	3-D Model not reflecting the current selection in TMJ screen. The 3D rendering view in the TMJ screen may not match the position of the condyle adjustments if the TMJ screen is exited and re-entered. Workaround: Re-adjust the condyle control to update the 3D rendering view to match.
1073	Add image from external file isn't proper. There are apparent reflections in the image that is displayed in the report. Image files inserted into report templates may show erroneous content at the right and bottom edges of the image. Workaround: Pad the inserted image with white content at the right and bottom edges to avoid this effect.
1088	The reports printed page is not the same as the on screen page when the same size paper is chosen. Margin settings for a report may result in clipped content in printed output. Content positioned close to any of the page-boundaries may be clipped by margin settings when printing. Workaround: Reposition content away from edges.
1121	Landscape pages in Reports do not print out as landscape. Workaround: Change the page orientation to landscape using the printer properties button in the Print Report dialog.

ID	Known Issues
1147	The Legacy DICOM Exporter is not localized. This software is only available in English.
1158	When a report is generated from the TMJ screen, in some cases the size of the Axial view changes when the user (or the referring dentist) re-opens the report. Users should save and verify any TMJ reports, and adjust as necessary.
1159	Due to numerical rounding, the condyle angles shown on the TMJ screen may not exactly match those shown on the TMJ report. Since the two images may be drawn on grids of different sizes, the overlay graphics may fall on slightly different pixels, resulting in slightly different angles. Both measurements are correct for their respective images. Discrepancies of up to 0.4 degrees have been seen.
1271	Measurements on cross-sections from the implant screen may be clipped in reports. This happens with the Life-Size setting and 5 images per row. Workaround: Use 4 images per row.
1282	Patient names containing characters which are not allowed in filenames (i.e. *?|/<>:") cannot be used in DICOM exporting because the patient name is used in the exported file name.
1305	The Study Instance UID sent by an RIS or HIS in DICOM Modality Worklist is not used. Instead, a new Study Instance UID is generated for any studies that are created for the patient.
1352	Previews from previous CT scans are sometimes missing on the Acquisition/Reconstruction screen during retro-reconstruction.
1363	When a sharp filter is applied to the TMJ screen, the left side data may appear darker or lighter than the right side, and there is no way to independently adjust the Window/Level.
1369	When a large rotation is applied to any two orthogonal views on the Preview Screen, a small distortion in the orthogonal views may become visible.
1371	Deleted HU measurements may reappear on the Preview Screen Panoramic Image after switching between arches.
1387	The irregular or straight line on the MPR screen disappears when switching to the Preview Screen and back to the MPR screen.
1405	The Panoramic Image on the Implant Screen is not displayed when selecting Automatic Arch detection after selecting None for a panoramic method.
1424	Printing reports containing color images imported from external image files may result in incorrect colors being printed for the imported images. Patient images included in the report from the associated study are unaffected.

Chapter 6 VDE 0751-1 Safety Checks (Germany Only)

Safety Checks

The safety checks in this chapter must be followed for systems installed in Germany in accordance with VDE 0751-1.

Safety checks are required after:

- System Repair
- Recurrent Maintenance and Interval (2 years)
- System Modifications
- Initial Installation

Qualified personnel must perform these tests. Qualifications include training on the subject, knowledge, experience, and acquaintance with the relevant technologies, standards and local regulations. The personnel assessing the safety must be able to recognize possible consequences and risks arising from non-conforming equipment.

Responsibility is accepted for the safety, reliability, and performance of the component suppliers by Imaging Sciences International provided:

- Installations, upgrades, adjustments, changes, or repairs are performed by service technicians trained by ISI or authorized 3rd parties including personnel of authorized distributors.
- The system is operated in accordance with the Operators Manual, including care and installation instructions.
- After repair, the requirements of VDE 0751-1 for safety testing and visual inspection are performed in full.

Visual Inspection

Perform a visual inspection of system and accessories (Reference VDE-0751 IEC 62353 Section 5.2) to include:

- Ratings of fuses that are accessible from outside
- Safety-related markings and labeling are legible and complete
- Integrity of mechanical parts
- Absence of any damage or contamination
- Required documentation is present and reflects the current revision of the system

Safety Tests

According to VDE7501-1, the following tests must be performed, and the main switch of the scanner must be turned on during measurement.

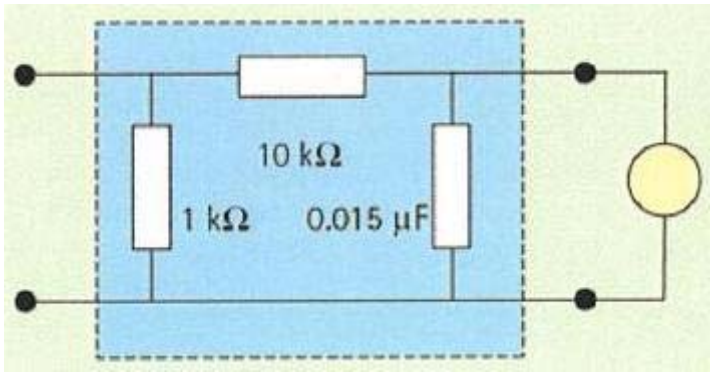
- Insulation Resistance
- Equipment Leakage Current
- Patient Leakage Current (Not applicable for this system)
- Protective Earth Resistance

Test Equipment/Forms Required

The following are required to perform the safety tests:

- ***Test Results Form*** or equivalent
- Enclosure Leakage Test Box (see circuit below)
- Digital multi-meter with mV scale, Fluke 8600A or equivalent
- Tool and Appliance Tester, Megger 235303 or equivalent

NOTE: The settings called out in the follow procedure correspond to the above-listed models. If you use different models, you may need to adjust the procedure according to the controls/indicators available on the models used.



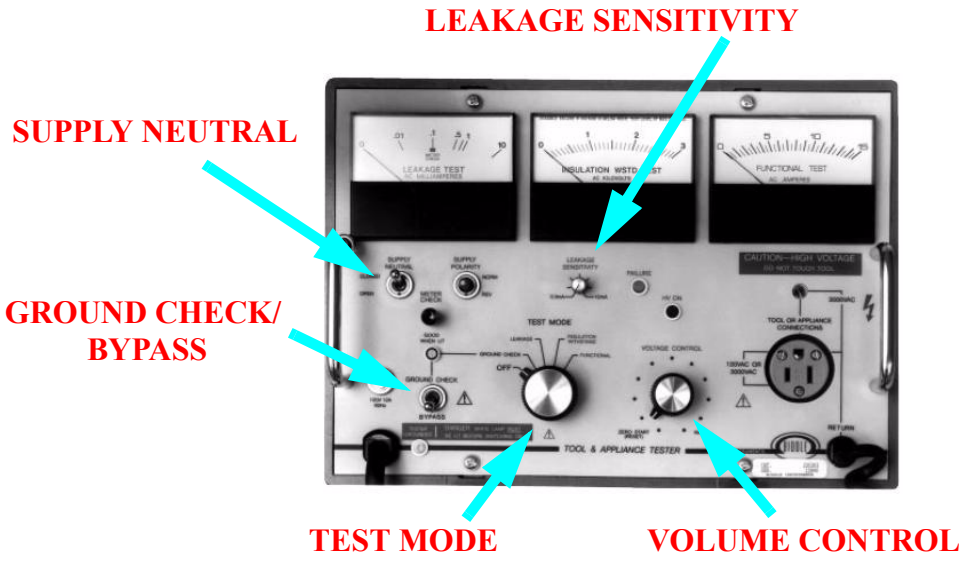
Enclosure Leakage Test Circuit

Procedure

Setup

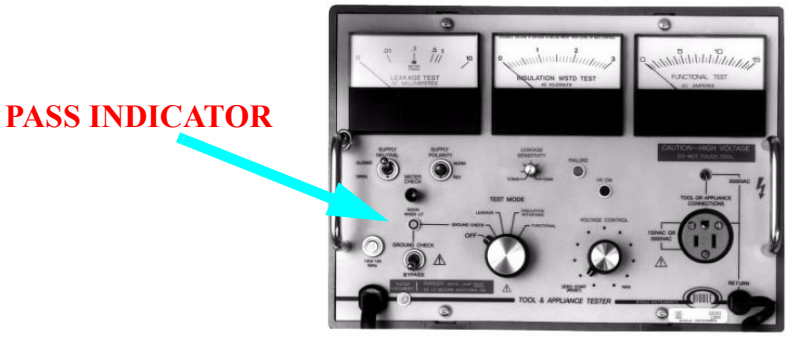
This procedure must be completed in sequence. Before plugging in any equipment, preset switches on appliance tester to:

- SUPPLY NEUTRAL – Set to Close
- GROUND CHECK / BYPASS – Set to Ground Check
- LEAKAGE SENITIVITY – Set to 12mA
- TEST MODE – Set to OFF
- VOLTAGE CONTROL – Set to Zero Start
- Disconnect PC Ethernet cable from back of scanner



Ground Test:

1. Plug in power to appliance tester.
    - White indicator should be on.
    - If not, STOP, and refer to the appliance tester manual.
2. Plug in scanner main power cord to appliance tester.
3. Clamp Return cable to scanner.
4. Switch on main breaker at back of scanner.
5. On appliance tester, set TEST MODE switch to GROUND CHECK.
    - Ground check pass indicator (green) should be lit indicating the test has passed.
    - If there is no light illuminated, the test has failed. STOP and fix problem.



6. Set GROUND CHECK/BYPASS switch to BYPASS. Tester ground indicator will go out.
7. Remove Return cable from chassis of scanner.
8. Turn TEST MODE to OFF.
9. If test has passed, record pass/fail on Test Results form.

Leakage Test (1)

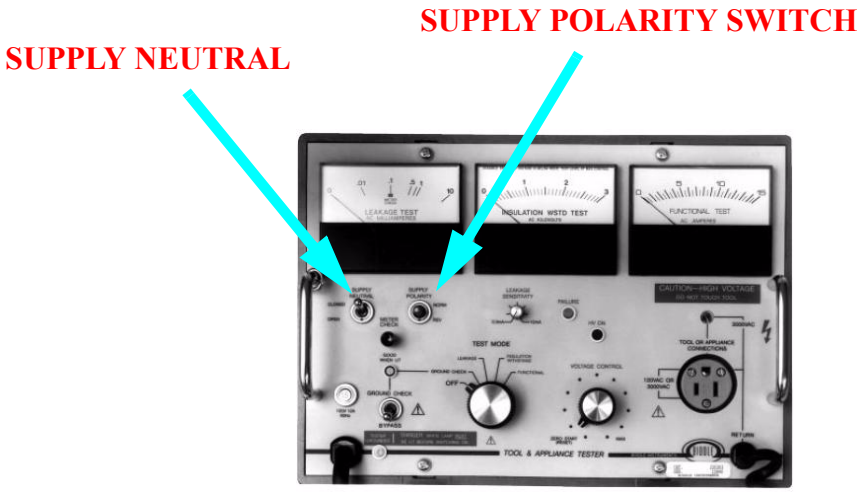
NOTE: For Leakage Test (1), take measurements from digital multi-meter.

10. Remove scanner power from appliance tester and back of scanner.
11. Connect enclosure leakage test box cables to:
    - Cables on the side of enclosure leakage test box.
        - Black cable to appliance tester ground (handle).
        - Chassis cable to scanner chassis ground.
        - Red cable is used to probe scanner.

- Connect power cord, with ground removed, from scanner to appliance tester.

12. Connect the digital multi-meter to the enclosure leakage test box.
    - Black (lo max) to green (enclosure) on enclosure leakage test box.
    - Red (V-ohms) to red (leakage) on enclosure leakage test box.
13. Switch GROUND CHECK / BYPASS to BYPASS.
14. Turn TEST MODE to LEAKAGE on appliance tester.
15. Set switches to:
    - Enclosure leakage test box - S7 Closed

- Appliance Tester - SUPPLY NEUTRAL Closed



16. Hold SUPPLY POLARITY switch to NORM. Turn scanner on, then probe scanner and record reading below.
17. Hold SUPPLY POLARITY switch to REV. Turn scanner on, then probe scanner and record reading below.
18. Set enclosure leakage test box and appliance tester switches to:
    - Enclosure leakage test box - S7 Closed
    - Appliance Tester - SUPPLY NEUTRAL Open
19. Hold SUPPLY POLARITY switch to NORM. Turn scanner on, then probe scanner and record reading below (machine should not turn on).
20. Hold SUPPLY POLARITY switch to REV. Turn scanner on, then probe scanner and record reading below (machine should not turn on).
21. Set enclosure leakage test box and appliance tester switches to:
    - Enclosure leakage test box - S7 Open
    - Appliance Tester - SUPPLY NEUTRAL Closed
22. Hold SUPPLY POLARITY switch to NORM. Turn scanner on, then probe scanner and record reading below.
23. Hold SUPPLY POLARITY switch to REV. Turn scanner on, then probe equipment and record reading below.
24. Turn TEST MODE to OFF.
25. Disconnect the enclosure leakage test box and connect the scanner power cord between appliance tester and scanner.

Supply Polarity Switch Position	**S7 Switch Position**	**Supply Neutral Switch Position**	**Limit mV**	**Leakage Reading (mV)**
Norm	Closed	Closed	100	
Rev	Closed	Closed	100	
Norm	Closed	Open	500	
Rev	Closed	Open	500	
Norm	Open	Closed	500	
Rev	Open	Closed	500	

Leakage Test (2)

NOTE: For Leakage test (2), take measurement from the appliance tester LEAKAGE TEST meter.

26. Turn TEST MODE to LEAKAGE.
27. Set appliance tester switch to:
    - SUPPLY NEUTRAL Closed
28. Hold SUPPLY POLARITY switch to NORM. Turn scanner on and record reading below.
29. Hold SUPPLY POLARITY switch to REV. Turn scanner on and record reading below.
30. Set appliance tester switch to:
    - SUPPLY NEURAL Open
31. Hold SUPPLY POLARITY switch to NORM. Turn scanner on and record reading below (machine should not turn on).
32. Hold SUPPLY POLARITY switch to REV. Turn scanner on and record reading below (machine should not turn on).
33. Record pass/fail results on Test Results form for both leakage tests.

Supply Polarity Switch Position	Supply Neutral Switch Position	Limit mV	Leakage Reading (mV)
Norm	Closed	0.5	
Rev	Closed	0.5	
Norm	Open	1.0	
Rev	Open	1.0	

Insulation Withstand Test

NOTE: For Insulation Withstand test, take measurement from the appliance tester INSULATION WSTD TEST meter.

34. Insure TEST MODE is OFF. Connect the scanner power cord between the appliance tester and scanner.
35. Set VOLTAGE CONTROL to ZERO START.
36. Set LEAKAGE SENSITIVITY to 12mA.
37. Set TEST MODE switch to INSULATION WITHSTAND.
    - HV ON indicator light should be on. If indicator is not ON, refer to manual.

38. Slowly turn the VOLTAGE CONTROL clockwise, set at a value of 1500 volts and maintain it for a period of one minute.

    During the test, be alert to these indications of failure:

    - Buzzer sounds and FAILURE indicator lights are on.
    - Sudden voltage drop; retarded or erratic INSULATION WSTD TEST meter reading.

39. If a failure occurs, set VOLTAGE CONTROL to ZERO START, set TEST MODE switch to OFF and repair scanner.
40. If scanner passes test, record pass/fail and voltage on Test Results form.
41. Turn VOLTAGE CONTROL to zero.

Functional Test

NOTE: For Functional test, take measurement from the appliance tester FUNCTIONAL TEST meter.

42. Set TEST MODE switch to FUNCTIONAL and turn on scanner.
43. Observe the FUNCTIONAL TEST meter.
    - If scanner draws more than 2A, turn TEST MODE switch to OFF and repair scanner.
    - If scanner passes, record pass/fail and amps reading on Test Results form.
44. Unplug scanner from appliance tester.

Test Results Form

Testing organization: Name of testing person:	Test before putting into service (reference value): ☐ Recurrent test: ☐ Test after repair: ☐
Responsible organization:	
Equipment:	ID-Number:
Type:	Production No./Serial Nr.:
Manufacturer:	Class of protection: I II Battery
Applied part type: B	Mains connection: [1] PIE NPS DPS
Accessories:	

Test: Measurement equipment:	Complies: Yes	No
Visual inspection:	☐	☐
Measurements:		
Protective earth resistance (Passes Ground Check)	☐	☐
Equipment leakage current (All readings equal to or below limit for Leakage tests 1 and 2)	☐	☐
Insulation resistance (Passes with no failure indicators) _____ kV	☐	☐
Patient leakage current (Not applicable)	☐	☐
Functional test (Passes - equipment operational) _____ amps	☐	☐

Deficiency / Note:

Overall assessment:

☐ No safety or functional deficiencies were detected.

☐ No direct risk, deficiencies detected may be corrected on short term.

☐ Equipment shall be taken out of operation until deficiencies are corrected.

☐ Equipment does not comply:
Modification / Exchange of components / Taking out of service - is recommended.

Next recurrent test necessary in 6 / 12 / 24 / 36 months

Name: _____ Date / Signature: _____

[1] PIE Permanent installed equipment
NPS Non-detachable power supply cord
DPS Detachable power supply cord

Chapter 7 System Schematics

WARNING

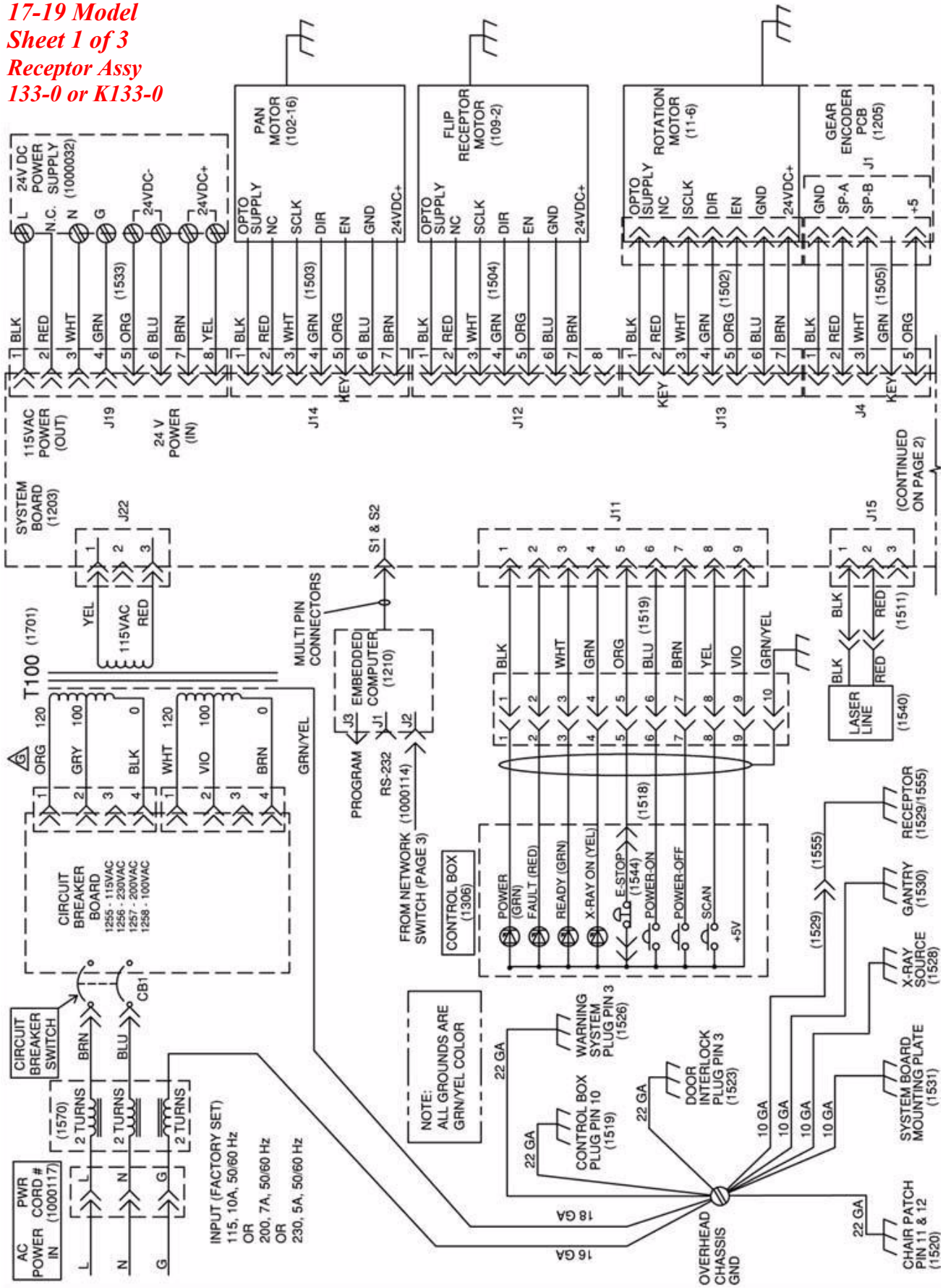
High voltage is present in the device. Remove power from device before removing covers or cables. To avoid personal injury from electrical shock, do not operate the system with any covers open or cables removed.

This chapter is used to provided system schematics. Ensure power is removed before servicing the device.

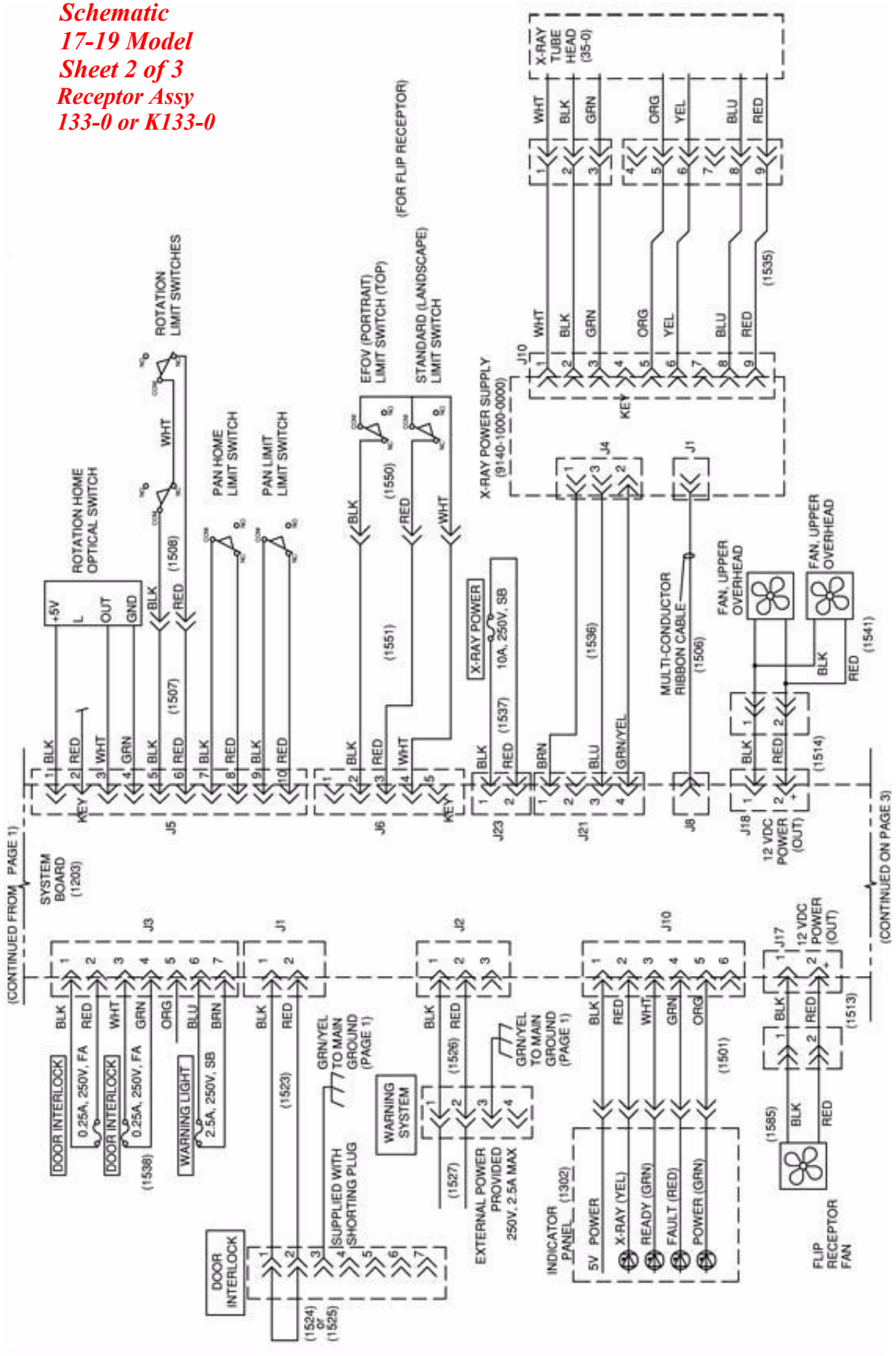
The following System Schematics are illustrated.

- 17-19 Model (Receptor Assy 133-0 or K133-0) pages 7-3, 7-4, and 7-5
- 17-19 Model (Receptor Assy 109-0 or K109-0) pages 7-6, 7-7, and 7-8
- 9-17 Model - pages 7-9, 7-10, and 7-11 (Receptor Power Cable 1553 / 1554)
- 9-17 Model - pages 7-12, 7-13, and 7-14 (Receptor Power Cable 10082607

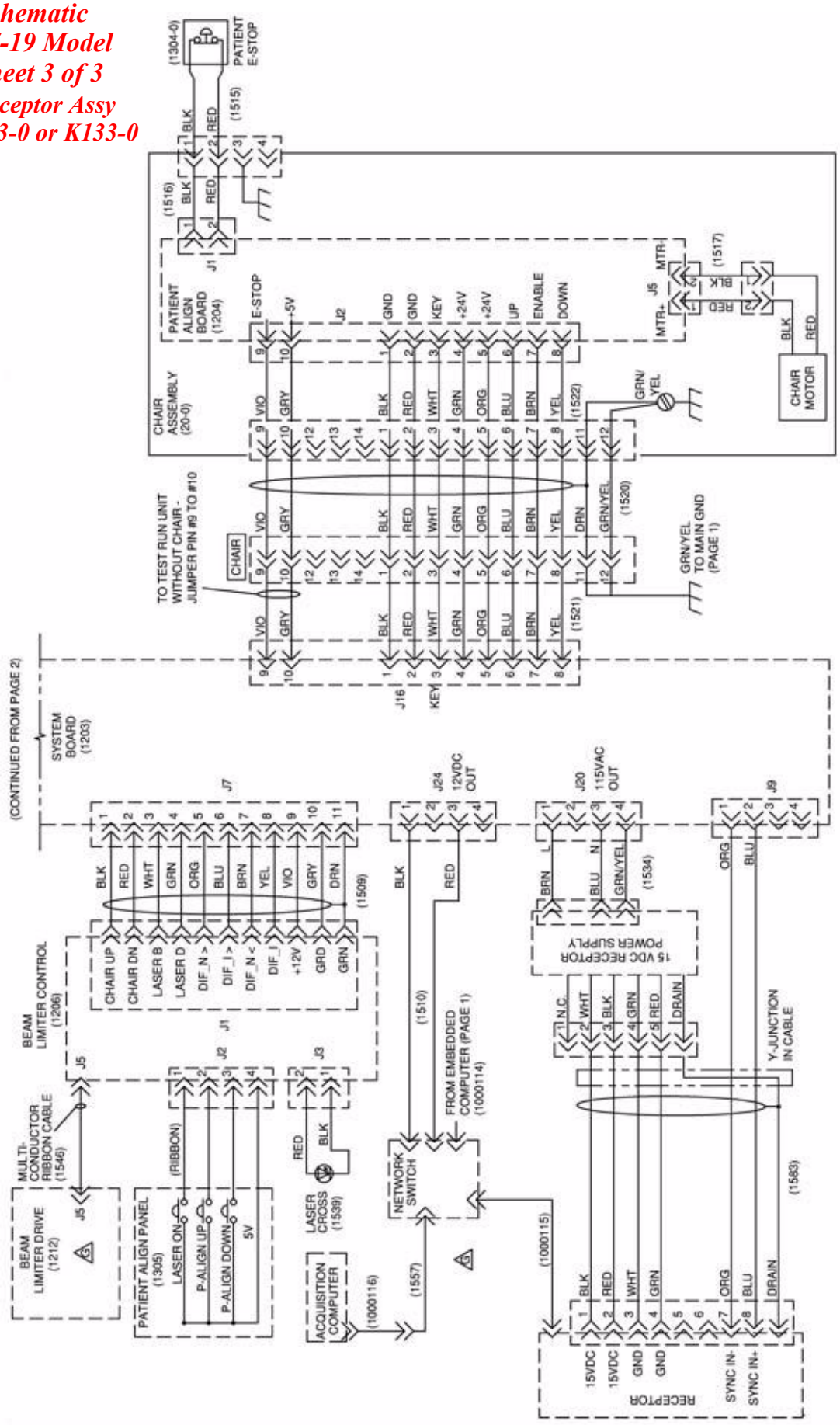
Schematic
17-19 Model
Sheet 1 of 3
Receptor Assy
133-0 or K133-0



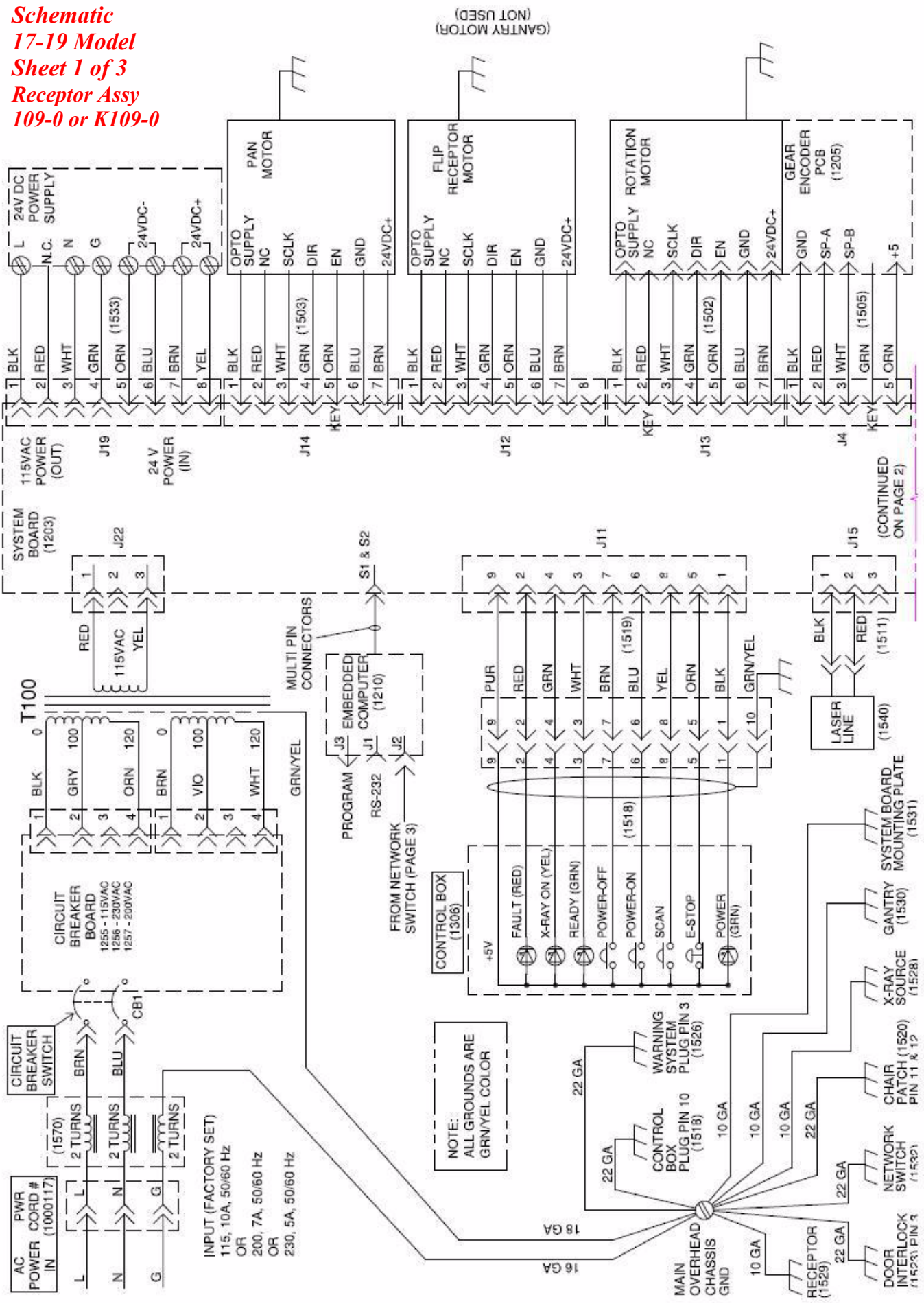
Schematic
17-19 Model
Sheet 2 of 3
Receptor Assy
133-0 or K133-0



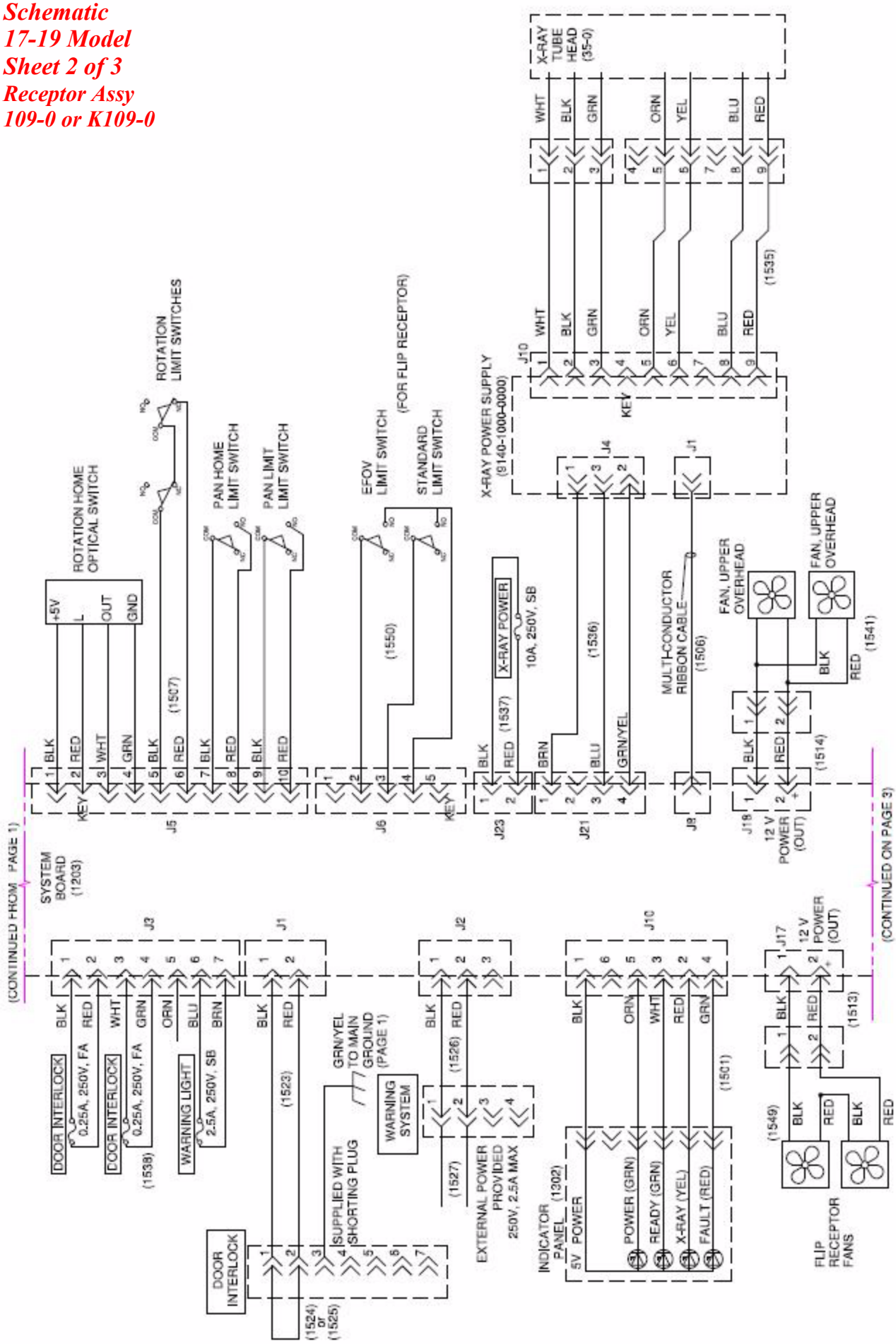
Schematic
17-19 Model
Sheet 3 of 3
Receptor Assy
133-0 or K133-0



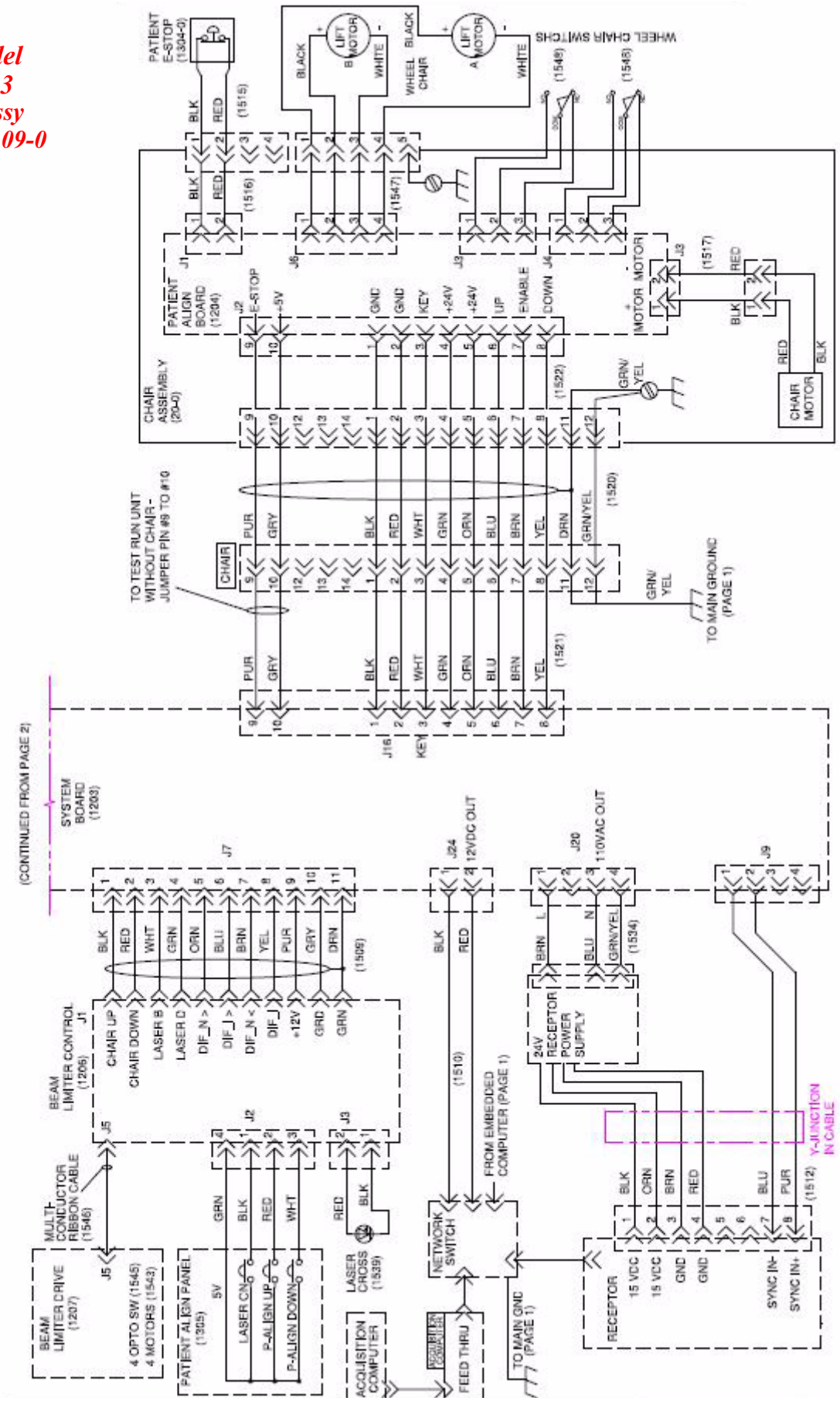
Schematic
17-19 Model
Sheet 1 of 3
Receptor Assy
109-0 or K109-0



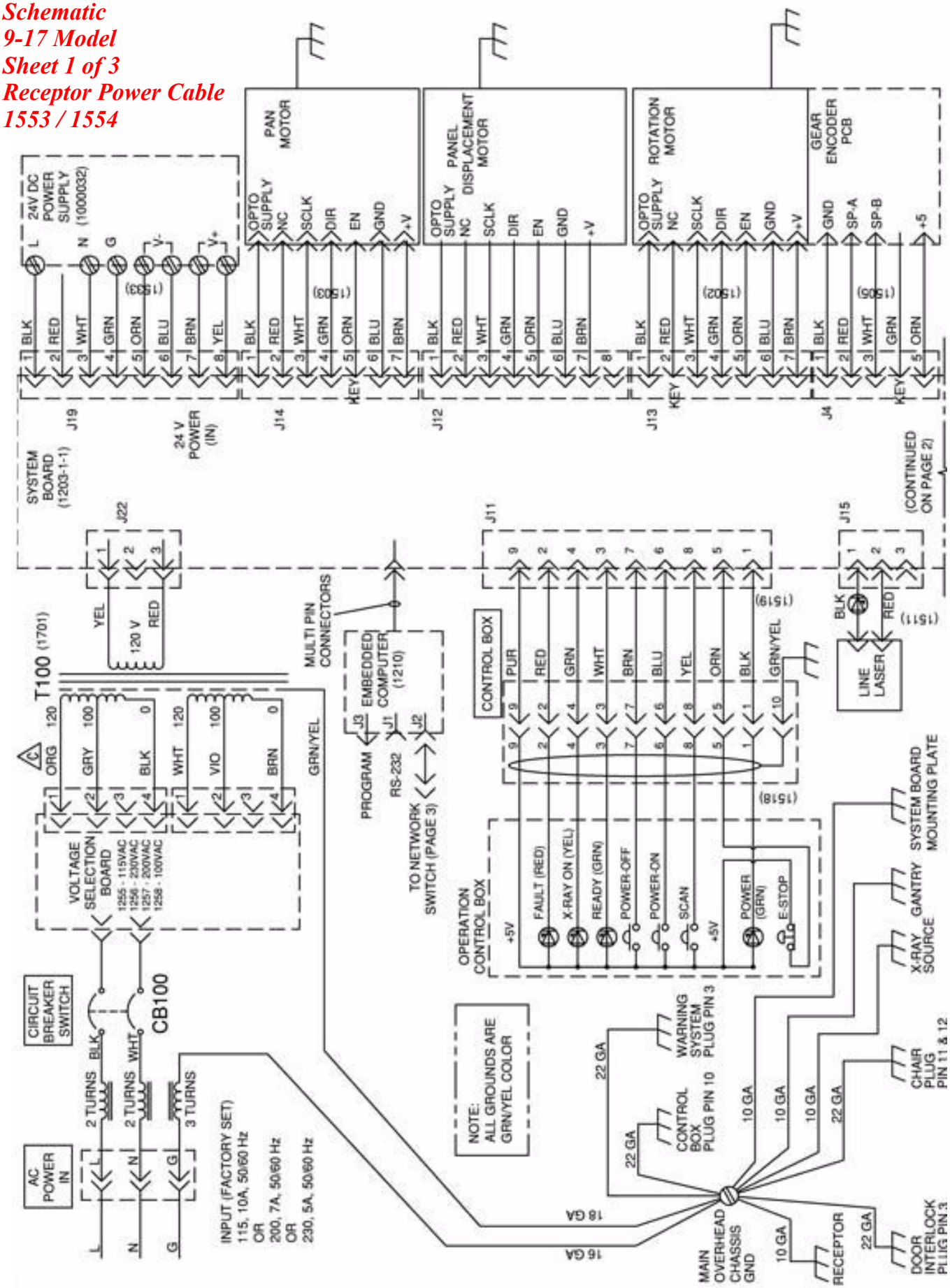
Schematic
17-19 Model
Sheet 2 of 3
Receptor Assy
109-0 or K109-0



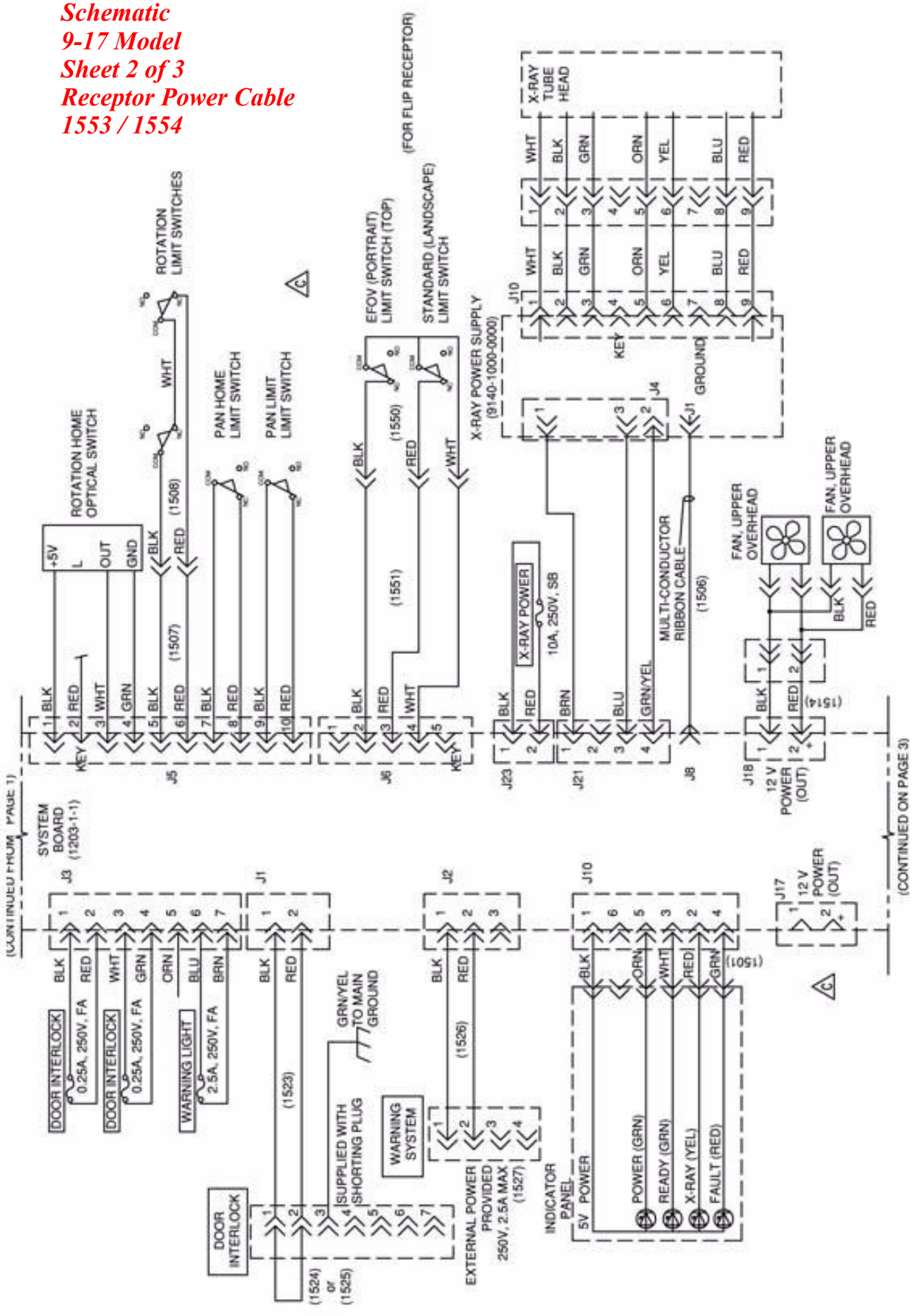
Schematic
17-19 Model
Sheet 3 of 3
Receptor Assy
109-0 or K109-0



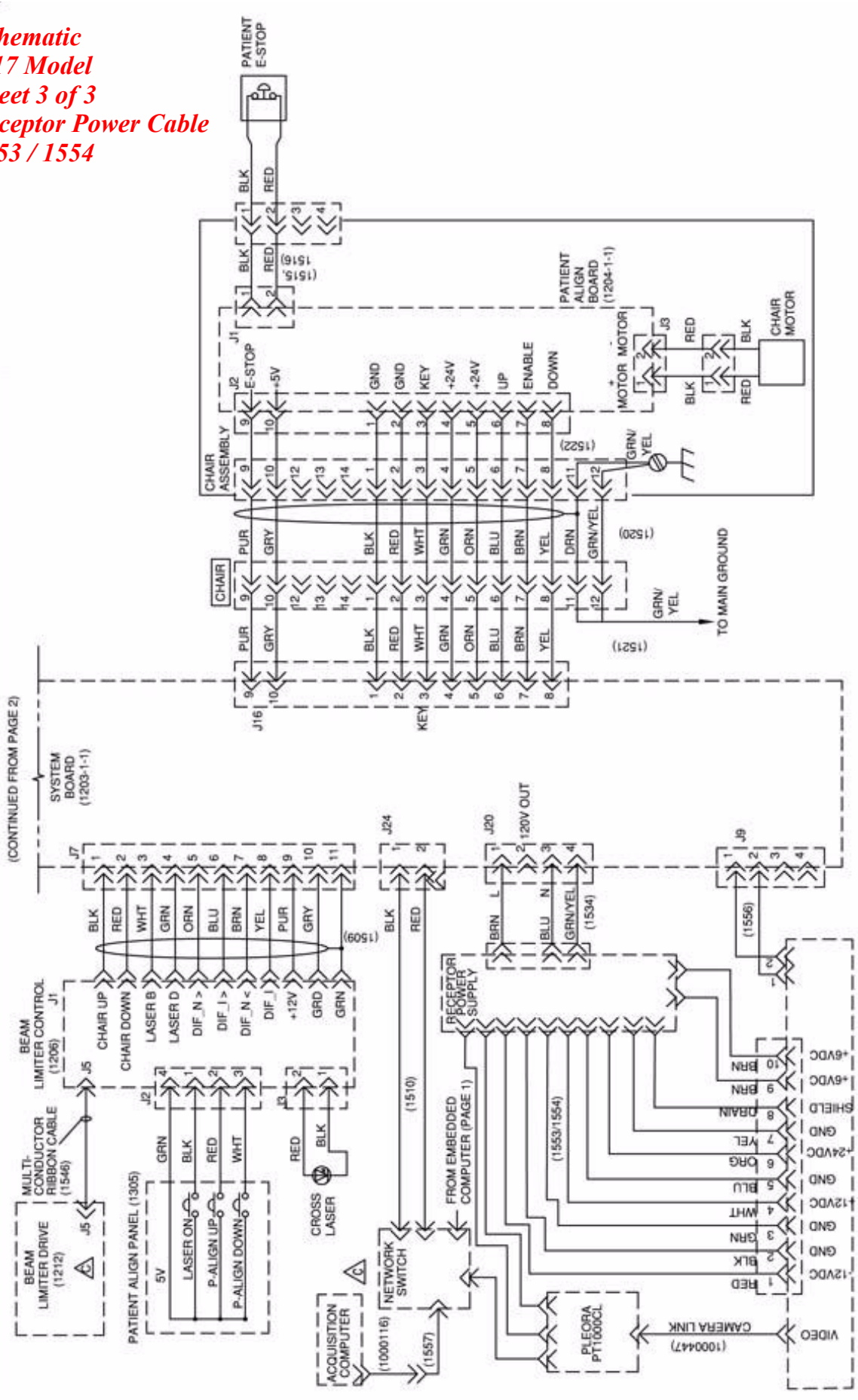
Schematic
9-17 Model
Sheet 1 of 3
Receptor Power Cable
1553 / 1554



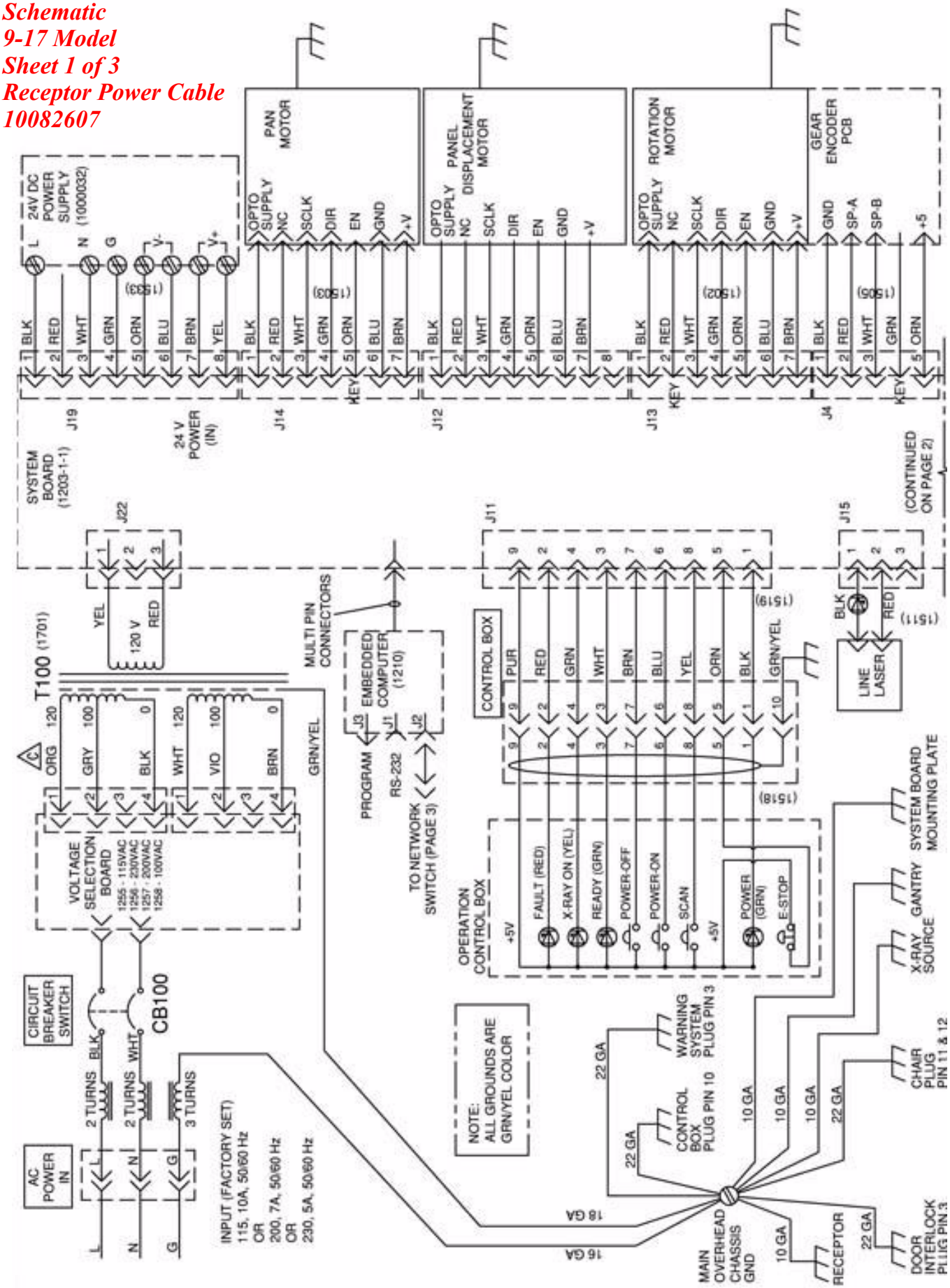
Schematic
9-17 Model
Sheet 2 of 3
Receptor Power Cable
1553 / 1554



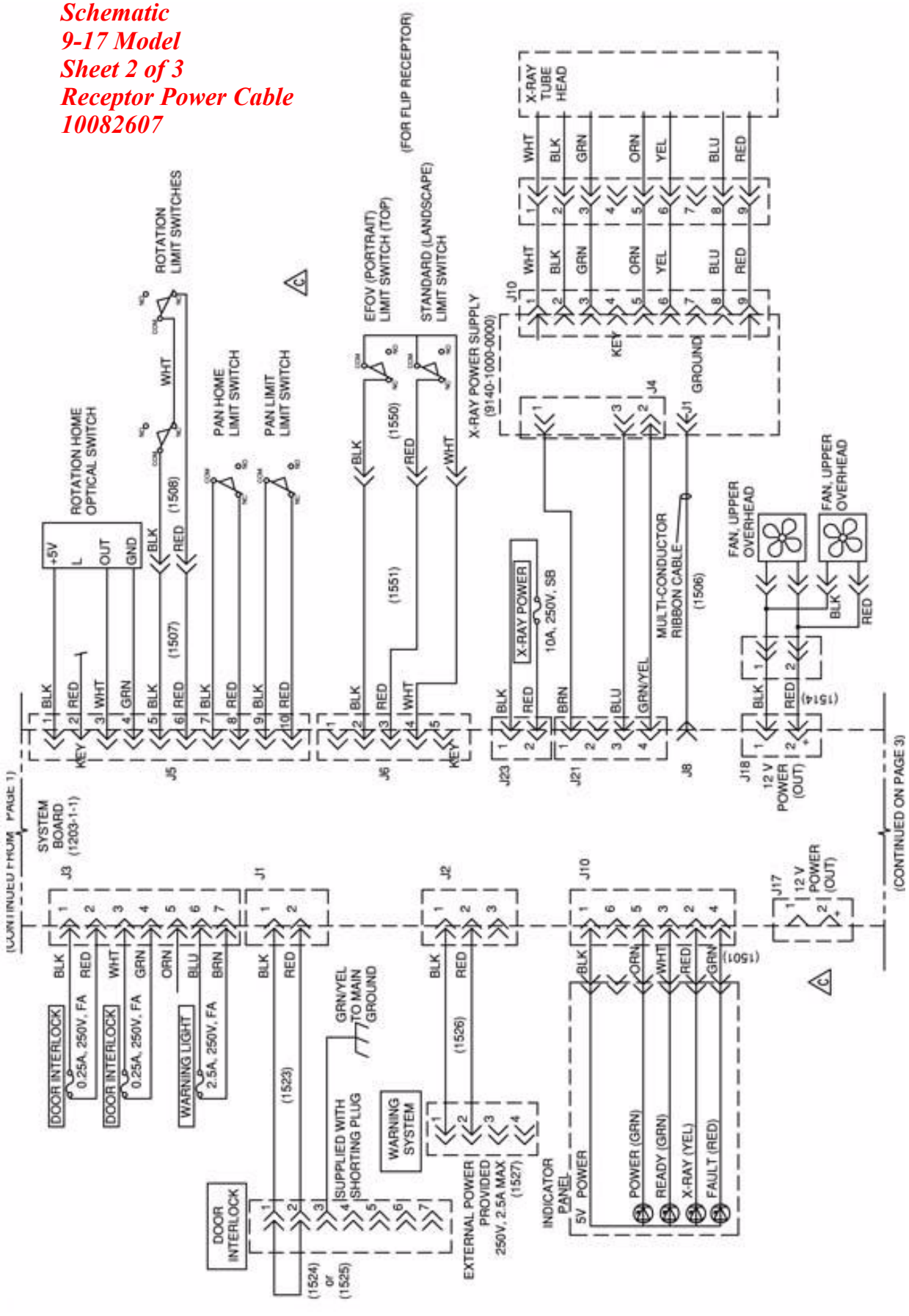
Schematic
9-17 Model
Sheet 3 of 3
Receptor Power Cable
1553 / 1554



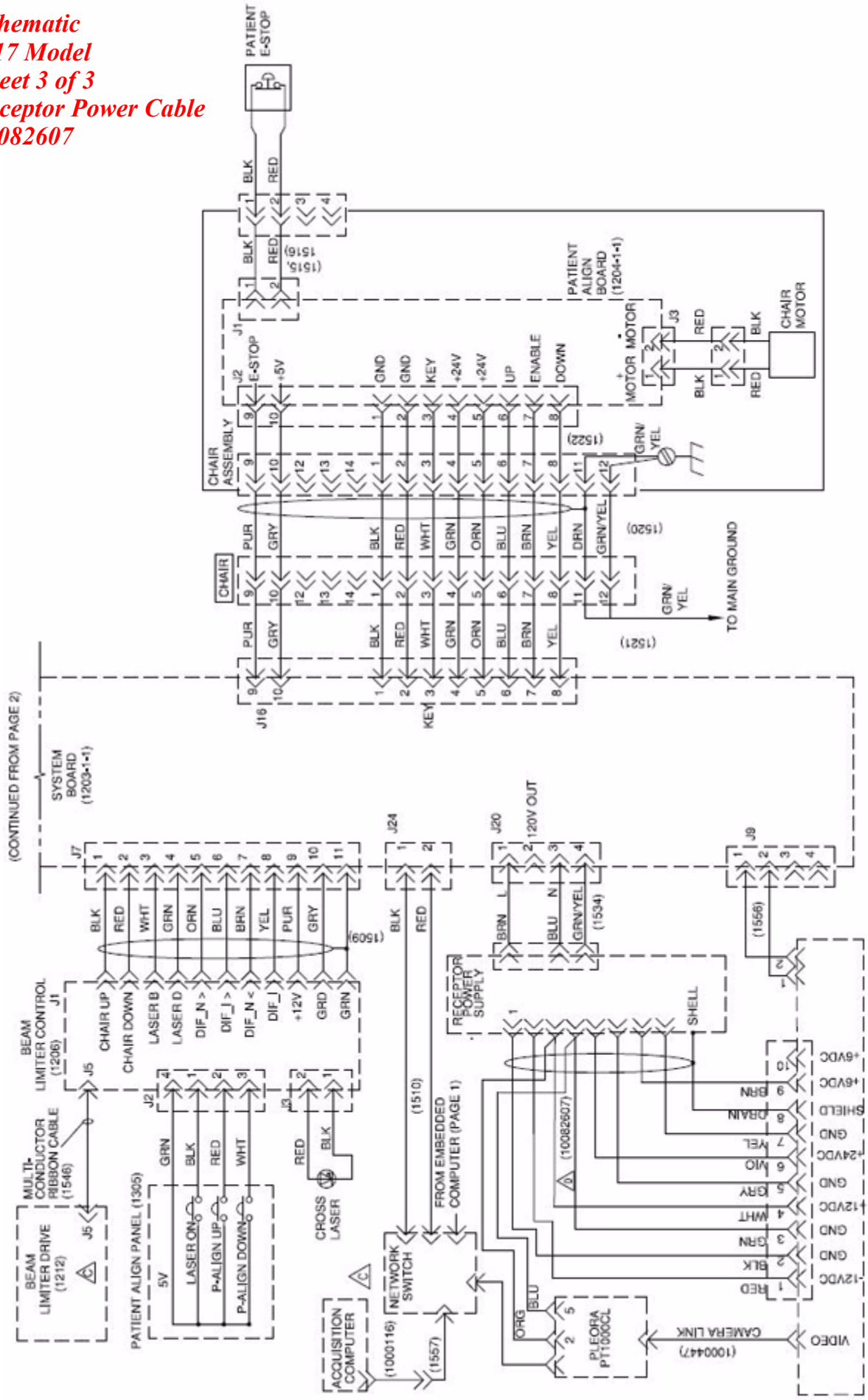
Schematic
9-17 Model
Sheet 1 of 3
Receptor Power Cable
10082607



Schematic
9-17 Model
Sheet 2 of 3
Receptor Power Cable
10082607



Schematic
9-17 Model
Sheet 3 of 3
Receptor Power Cable
10082607



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